Measuring Expenditure on Health-related R&D

HEALTH

OECD

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FOREWORD

This book originates from an exercise undertaken in co-operation between Statistics Canada and the OECD Working Party of National Experts on Science and Technology Indicators. Its objective was to build on the existing work at the OECD, supported by the *Frascati Manual*, to improve the coverage, quality and comparability of data available on health R&D for international comparison. As part of this exercise ten countries [Australia, Austria, Canada, Denmark, France, Israel, Norway, Spain, the United Kingdom (England) and the United States] provided papers on their national health R&D systems and funding data and a review of the main international sources was undertaken. An informal workshop was held on 10 March 2000 to discuss the main measurement issues revealed by these papers including:

- Identifying and comparing health-related R&D in government R&D budgets.
- Measuring the resources devoted to R&D in hospitals.
- Identifying the borderline issues of R&D associated with clinical trials.
- Measuring and comparing health-related R&D in the government, private non-profit and higher education sectors.
- Identifying and comparing health-related R&D in the business enterprise sector.
- Other classifications of health R&D.

The first part of the book identifies and illustrates the main problems of international comparability of the data on health-related R&D currently available from OECD and other international R&D and health data sources. It incorporates the discussion papers and gives many illustrations from national sources.

Part II covers the national papers which reveal some common preoccupations (notably measuring R&D in hospitals, and measuring R&D by persons with multiple activities spread over very long hours) and others caused by national specificities, such as employment practices or complex relations between the institutions and teams which make up the respective national health science and innovation systems.

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Part I

AN ASSESSMENT OF NATIONAL AND INTERNATIONAL PRACTICES FOR COMPILING DATA ON HEALTH-RELATED RESEARCH AND DEVELOPMENT

by

Alison Young
Consultant to Statistics Canada

Introduction

The demand for information

The importance of the contribution of science and technology to improving human health is widely accepted.

Science, technology and human health

Half of all the gains in human life expectancy of the past several thousand years have occurred in this century. Some of these gains have resulted directly from the improvements in economic and educational standards that have recently transformed the material lives of most - but far from all of the world's population. Improvements in income and education account, however, for only part of this century's remarkable improvements in health. At the turn of the century the people of a country with an income level of USD 5 000 per capita (in purchasing power adjusted for inflation) would have had a life expectancy of under 50 years; today the number is close to 75. Why this enormous difference after controlling for income? Important as income and education undoubtedly are, another factor - advance in scientific knowledge and its application both in creating powerful interventions and in guiding behaviour - has, perhaps, become more important.

Source: WHO (1996), *Investing in Health Research and Development.*

The advance in scientific knowledge mentioned above results from R&D activities. To date, there is not an established set of internationally comparable health-related R&D data, which can be used to describe and understand this phenomenon and to aid policy makers in priority setting. This first part of the book reviews the existing international sources and ongoing plans in order to identify what information on R&D is already available or in the pipeline and examines the main problems of international comparability with illustrations for selected countries.

It reviews three frameworks and sources of data on spending on health-related R&D:[1]

- Science and technology policy, indicators and underlying survey.
- Health policy, indicators and underlying survey.
- Special studies of health research.

In the first two cases the most that can be expected is to get a general picture of the level and structure of health-related R&D within the statistical framework concerned. In the third case a greater attempt may be made to obtain full coverage and to use specific classifications.

A framework for international comparisons

Since the review is of existing national and international surveys and sources one cannot begin with firm definitions of health R&D and its main components. What are needed are gauges for measuring the coverage and comparability of the data available.

The National Health Science and Innovation System

First it is useful to start with an overall view of the way health R&D is organised. Each country may be said to have a National Health Science and Innovation System (NHSIS), *i.e. the set of institutions, teams and individuals who, jointly and individually, create, store and transfer the knowledge, skills and artefacts which define new and improved health products and interventions and more efficient ways of delivering them.*[2] This system operates at two levels, the distinct institutions and major programmes and below them a complex network of topics, teams and projects which are the actual "elements in a collective system of creation, transfer, and use"[3] of health related knowledge.

The same "core" types of institutions (medical research councils[4], medical faculties, hospitals, pharmaceutical companies, health-related charities etc.) exist in most countries. However, the way they are organised and their relative importance varies from country to country. Furthermore there are other institutions which fund or perform some health R&D although this is not their main activity. These "peripheral health R&D institutions" may be mainly involved in healthcare and do (or are expected to do) relatively little R&D (non-university hospitals). They may do some health related R&D in connection with their main activity (health and safety at nuclear establishments, military medicine by the armed forces) or do basic research which may have health applications (general research councils). R&D surveys may cover only the core institutions, or also the peripheral ones. Some very detailed ones may reach "topics, teams and projects".

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[1] There are other international sources and frameworks. This paper does not examine data on biotechnology R&D which is the topic of another Statistics Canada/OECD activity.

[2] Based on Metcalfe (1995) as quoted in OECD (1999a) and Global Forum for Health Research (1999).

[3] Smith (1996) as quoted in OECD (1999a).

[4] Given recent changes "Health Research Councils" would be more appropriate. For example, since 1992 the Australian Health Research Council, and in 2000 the Canadian Institutes of Health.

Distinguishing between R&D and non-R&D activities

Different sources place the borders of health R&D at different points. The first boundary is between R&D and other activities.

The definition of R&D for survey purposes dates back to the United States in the mid 1950's. It has changed little since[5]. The version used by OECD/Eurostat/UNESCO is as follows:

> Research and experimental development comprise creative work undertaken on a systematic base in order to increase the stock of knowledge, including knowledge about man, culture and society, and the use of this knowledge to devise new applications

Virtually all the sources examined in this paper use this definition or something very like it as a point of departure. R&D can be distinguished from other activities carried out in the Health Science and Innovation System. These other activities include: education and training; other scientific and technological activities, (scientific and technical information services; general purpose data-collection; testing and standardisation; feasibility studies; patent and licence work; policy-related studies; routine software development); other industrial activities leading to technological innovation and administration and other supporting activities. In the case of health-related R&D it must also be distinguished from regular medical care activities. Sources may attempt to distinguish R&D from all these activities, may identify R&D only where it is an independent activity, or may cover both R&D proper and those related S&T activities which are needed to build up the national capacity to undertake health-related R&D.

Distinguishing between health-related R&D and other R&D

In the widest sense we are interested in all R&D which is relevant to human health. Here there are no generally accepted international definitions or guidelines on coverage. "There are few (if any) areas of investigations which can "logically" be excluded from possible relevance to health – perhaps cosmology" (Wilk, 1996). Coverage differs between sources, depending on the aims of the designers/users and also on the type of survey approach adopted. The term "relevance" can be defined using different criteria and its coverage can be extended along several axes.

- How far "back" up the chain the source concerned goes for *long term research*, which may have health applications, notably in the field of biology.

- How far it includes R&D on *the risk factors* for ill-health (smoking, diet, social exclusion, etc.)

- How far it includes R&D on methods of *managing and delivering* new and improved health products and interventions and the associated government policies.

Apparent and actual expenditure on health-related R&D

Given the lack of an agreed set of high quality health R&D data to underpin international comparisons, those seeking for such data have to compile them from various international sources. In doing so they are reduced to picking out the immediately available and obvious health-related R&D series and treating them as proxies for the health R&D indicators they would really like to compare between countries. This report examines whether these "apparent health R&D expenditure" series are, in fact, satisfactory proxies by comparing them with the more complete health R&D series quoted in the national contributions to the informal workshop and with data from selected national and international publications. At this stage it has only been possible to illustrate the problems concerned for ten volunteer countries: Australia, Austria, Canada, Denmark, France, Israel, Norway, Spain, the United Kingdom (England) and the United States.

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[5] This general definition first appeared in the second version of the *Frascati Manual* published in 1970.

Plan of Part 1

The first port of call for persons looking for data on health R&D is often the Government Budget Appropriations and Outlays for R&D (GBAORD) tables published by OECD and Eurostat. The prime health-related series in this source pose serious problems of comparability as is shown in Chapter 1. Others are interested in building up "Health GERD"[6] from the results of international surveys of R&D reported by performing firms and institutions. Chapter 2 reviews these international sources and also the national efforts reported to the Workshop. It distinguishes between health-related R&D in the market and non-market sectors. Chapter 3 presents two areas, clinical trials and R&D in hospitals, where national practice is changing and where the international guidelines for R&D surveys, known as the Frascati manual, (OECD, 1994), managed by the Working Party of National Experts on Science and Technology Indicators (NESTI), are not currently very useful. Chapter 4 presents data on health R&D collected in two quite different frameworks, health accounts (OECD) and related to the disease burden (associated with the WHO). Annex 1 gives an extensive bibliography and reading list.

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[6] Gross Domestic Expenditure on R&D, the accepted international measure of total national R&D spending.

Chapter 1

IDENTIFYING AND COMPARING HEALTH RELATED R&D IN GOVERNMENT BUDGET APPROPRIATIONS AND OUTLAYS FOR R&D: GBAORD

by

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General specifications of GBAORD

One way of measuring R&D expenditure is to approach the funders of the R&D. In the OECD/Eurostat system this is only done for central (federal) government-funded R&D using data derived from budgets. This essentially involves identifying all the budget items involving R&D (including payments to abroad) and estimating their R&D content. The sum of total government funds thus measured is referred to as Government Budget Appropriations or Outlays for R&D, GBAORD. These estimates are less accurate than the performance based data described in the next chapter but they are more timely and as they are derived from the budget they can be linked to policy issues by means of a classification of goals or objectives.

The general classification by socio-economic objectives

The 12 category classification used at OECD shown in Box 1.1 is a simplified version of a more detailed one, known as NABS,[7] developed and applied by EUROSTAT, which is the lead organisation for this type of data (Eurostat, 1994). The OECD classification also draws on a set of very similar definitions established by the Nordic countries (Nordforsk, 1975) which is still used in Nordic S&T statistics publications although most of these countries have joined the EU or become associated with Eurostat activities (and thus also report using NABS) and on the national classifications in other major OECD countries, notably the United States. This OECD classification operates mainly at the level of main categories with subcategories only where these are needed to ensure overall consistency with the chapters of NABS. NABS has systematic subcategories at two and sometimes three digit level allowing more possibilities of identifying health-related R&D funding.

The vast majority of OECD countries report GBAORD broken down by main socio-economic objective to OECD (Directorate for Science, Technology and Industry) annually, as do the selected non-member countries for which R&D data are collected by the Directorate. This data is not yet available from Turkey or from several of the most recent members (Hungary, Korea, and Poland) and only intermittently from Switzerland. The data are stocked in the R&D databases and are published as time series in *Basic Science and Technology Statistics* (OECD, annual a). All the EU countries report GBAORD at main chapter level to Eurostat as do Norway, Iceland and the European Commission. The response for subcategories varies. Eurostat publishes the data annually, showing two years for chapters and only one year for the detailed data (Eurostat, annual).[8]

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[7] Nomenclature for the analysis of science budgets.

Box 1.1. **The OECD classification by socio-economic objective (with the corresponding NABS chapters)**

1. Development of agriculture, forestry and fisheries (NABS Chapter 6).
2. Promotion of industrial development (NABS Chapter 7).
3. Production and rational use of energy (NABS Chapter 5).
4. Development of the infrastructure (NABS Chapter 2).
5. Control and care of the environment (NABS Chapter 3).
6. Health (excluding pollution) (NABS Chapter 4).
7. Social development and services (NABS Chapter 8).
8. Exploration and exploitation of earth and atmosphere (NABS Chapter 1).
9. General advancement of knowledge.
    - 9.1 Advancement of research (NABS Chapter 11).
    - 9.2 General University Funds- GUF (NABS Chapter 10).
10. Civil Space (NABS Chapter 9).
11. Defence (NABS Chapter 13).
12. Not specified (NABS chapter 12).

Source: *Frascati Manual* (OECD, 1994).

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[8] The most recent (2000) edition of the publication no longer includes the table on two-digit categories. The data for 1998 in the present chapter were obtained from the Chronos database.

Current international reporting of health-related R&D

GBAORD broken down by socio-economic objective (SEO) as collected by OECD has only one specific health related category, *Health (excluding pollution)*, defined as follows:

Health (excluding pollution)

"This category covers R&D programmes directed towards the protection and improvement of human health. It includes R&D on food hygiene and nutrition; radiation used for medical purposes, biochemical engineering; medical information; rationalisation of treatment and pharmacology (including the testing of medicines and the breeding of laboratory animals for scientific purposes): as well as research relating to epidemiology, prevention of industrial diseases and drug addiction."

Source: Frascati Manual (OECD, 1994).

The Eurostat/NABS system (Eurostat, 1994) has the equivalent category (Chapter 4) *Protection and improvement of human health,* plus two obviously relevant sub-categories – *medical sciences* in Chapter 11 *other non-oriented (OECD Advancement of Research*) and *medical sciences* in Chapter 10 *General University Funds* (see Annex 2).[9] Note that the *Frascati Manual* (OECD, 1994) recommends that both advancement of research and GUF should be broken down by main field of science, rather more strongly for GUF than for advancement of research.[10] An optional table for national detail was included in the OECD R&D questionnaire but with virtually no response. OECD also requests sector of first destination of GBAORD. Here again, response is very low.

The NABS system also has two health-related detailed (3 digit) sub-categories of Chapter *Promotion of industrial development: pharmaceutical products* (NABS 7.4.2) (a sub-category of 7.4 chemicals) and *manufacture of medical and surgical equipment and orthopaedic appliances* (a sub-category of 7.9 instrument manufacture).

Table 1.1 shows how many countries actually report these data to the two organisations. The vast majority of OECD countries supply GBAORD for health as a one-digit category. However, only about half the countries reporting to Eurostat give details on the medical sciences for advancement of research and for GUF.

---

[9] In most OECD countries, education ministries pay general grants to higher education institutions for education/R&D. It is up to the institutions and staff concerned to allocate these resources between different activities. General University Funds (GUF) are the (often) estimated costs of the R&D component thereof.

[10] The NABS system applied since 1993 identifies ten fields of science and technology: mathematics and computer sciences; physical sciences; chemical sciences; biological sciences; earth and related environmental sciences; engineering sciences; medical sciences; agricultural sciences; social sciences; humanities. The OECD groups the first five of these, giving six major fields: natural sciences, engineering, agricultural sciences medical sciences, social sciences, humanities. The Nordic GBAORD methodology also recommends a breakdown of total Advancement of knowledge into these six fields.

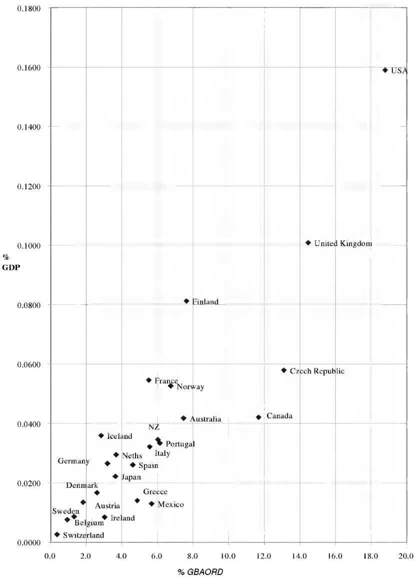
Table 1.1. **Availability of data for health-related items of GBAORD by socio-economic objective**

	Health objective		Adv. of knowledge: medical sciences		Industrial development		Destination
	Total	Sub-classes	Research	GUF	Drugs	Instrument	
Australia	X						
Austria	X						O
Belgium	X						O
Canada	X						O
Czech Republic							
Denmark	X		O	O			
Finland	X		X	X			
France	X						
Germany	X	X	X	X	X	X	X
Greece	X	X	X	X	X	X	
Hungary							
Iceland	X						
Ireland	X	X	X	X	X	X	X
Italy	X	X	O		X	X	
Japan	X						
Korea							
Luxembourg							
Mexico	X						O
Nether.	X	X	X	X	X	X	
New Zealand	X						
Norway	X						X
Poland							
Portugal	X	X					O
Spain	X	X	X	X	X	X	X
Sweden	X						
Switzerland	O						
Turkey							
U.K.	X	X	X	X	X	X	
U.S.A	X						
E. Commission	X	X	X		X	X	
Israel	X						
Romania	X						
Russia	X						
Slovak Republic	X						
Slovenia	X						
Numbers							
Members	24	9	10	8	8	8	9
Observers etc.	5						

X: reasonable series.
O: Occasional data points.
Source: OECD R&D database and Eurostat (annual) November 1999.

Figure 1.1. **Apparent government health R&D funding, 1998**

Health as primary objective, % of GBAORD and % of GDP



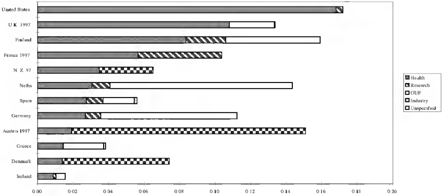
Source: OECD R&D database February 2000.

Effect of including additional sub-categories (SEOs)

Persons using OECD S&T publications as a source of data on government support for health-related R&D tend to use the *Health excluding pollution* category in GBAORD as a proxy for total government funding of this area (Figure 1.1) not realising that it only covers programmes for which this is the *primary purpose*. As can be seen from Figure 1.2, where selected EU countries for which additional data are available, are ranked in descending order for the health objective as a percentage of GDP, the picture can be very different if support for the *medical sciences* via advancement of research and via GUF is included. The additional funding via promotion of industrial development is minor. On this wider measure, the governments of Finland and Austria approach the United States Federal government as the highest funder of health related R&D as percent of GDP, followed closely by the Netherlands.[11]

Figure 1.2. **Effect of including other health-related NABS categories in health GBAORD, 1998**

% GDP



Source: Eurostat Chronos database and national publications (Austria, Denmark, New Zealand, United States).

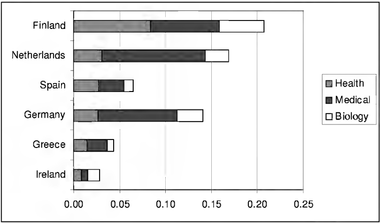
In Figure 1.2, we used medical sciences as a proxy for health-related R&D funded for the advancement of knowledge. In France and the United States the GBAORD data available for advancement of research do not distinguish between medical sciences and other life sciences. The Eurostat NABS series for recent years do permit one to break out biological research in advancement of research and in GUF but full responses are available for only half a dozen countries (See Figure 1.3). The effect is not as important as for the medical sciences.

---

[11] In earlier versions of this paper, the comparison was made for 1995. At that time, only Austria approached the United States. Since then, both Finland and the Netherlands have changed data coverage, Finland by improving the coverage of hospitals and the Netherlands by changing the method of calculating GUF.

Figure 1.3. **Health related GBAORD as % of GDP, 1998**

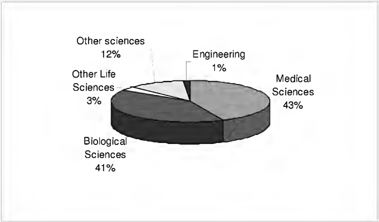
Effect of including biological sciences and medical sciences from advancement of knowledge.
Selected countries reporting to Eurostat



Source: Eurostat Chronos database.

It is difficult to decide whether or not one is justified in including all biological research from advancement of knowledge in health-related GBAORD, let alone to find a method of estimating the part that is health-related. The practical problem is that similar biological research will be included if funded by health research agencies that are classified in health as an SEO.

Figure 1.4. **National Institutes of Health: Research obligations by field of science and technology, 1997**



Source: Federal Funds for Research and Development 1997-99 (National Science Foundation, annual a).

Example: In the *United States,* as can be seen from Figure 1.4, the National Institutes of Health (NIH), which is the major component of health as an SEO, funds almost as much research in the biological sciences as in the medical sciences proper.

Reasons for different patterns of support for health R&D in the GBAORD data

Problems of international comparability are caused by differences in the coverage of GBAORD as a whole and in how the R&D funding data is distributed between objectives in the national surveys/compilation exercises.

Coverage of GBAORD

Level of government

GBAORD data are collected for Central/Federal government. The Frascati manual suggests that provincial government should also be included, if significant. Germany (and Mexico since 1997) are the only OECD countries with a federal system of government to do so. Provincial/State government funds are excluded from GBAORD as reported to OECD for Australia, Austria, Canada and the United States. For Austria and the United States data is also available for health-R&D funding reported by state/provincial government. For Australia and Canada, one must turn to the health-GERD tables discussed in the next chapter for an idea of the role of state/provincial government.

> *Example i).* In *Austria,* the *Länder* governments finance nearly one quarter of combined GBAORD for health as a SEO (1999 National coverage).
>
> *Example ii).* In the *United States* in 1995, State government direct support for health as an SEO totalled USD 244 million, rising to perhaps over USD 600 million if support for biological sciences via the national equivalent of Advancement of research is included. Together this represents about 4% of the wider total shown in Figure 1.5. (Data from Coburn, 1998, Jankowski, 1999, National Science Board, 2000).[12]
>
> *Example iii).* In *Canada* provincial government supplied nearly 30% of total government direct support for health in 1998 (Table 7.1).
>
> *Example iv).* In *Australia,* in 1996-97 state governments financed nearly 20% of public funds for health GERD: SEO approach (Table 5.4).

The distribution of responsibilities between different levels of government may also complicate the issue, even in countries without federal constitutions. For example, in Denmark R&D funding by municipal and county government is not included in GBAORD. About 90% of these funds go to support R&D in hospitals. If included they would almost double government funding for health-related R&D.

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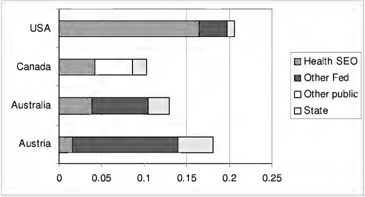
[12] The wider total for 1997 covers obligations for the equivalent of health as an SEO as reported to OECD, health-related R&D obligations as estimated by the National Institutes of Health as in Table 14.1, funding of R&D plant by the Department of Health and estimated funding by state government via health and support for the science base.

Figure 1.5. **Effect of including state/provincial government and other public funds in health-related GBAORD**

% GDP 1997 or nearest year



Source: National contributions and publications.

Some core institutions of the NSIS may be excluded from GBAORD because they do not receive any R&D support direct from government or because they are not thought to do significant amounts of research. In the past this may have been true for some, especially non-university, hospitals.[13] The treatment of GUF also varies.

> *Example i).* In the *United Kingdom* full support for R&D in National Health Hospitals was included in GBAORD for the first time in 1995-96. This raised funding of health as a SEO by about 45% from nearly GBP 400 million in 1994-95 to over GBP 750 million in 1995-96 (OECD, annual a).
>
> *Example ii).* In *Canada* in the national approach GUF is credited to the Higher Education Sector as a source of funds. When reporting to OECD 67% is treated as public GUF. In the health case this would come to about 20% of the wider total. Furthermore health GERD includes R&D in hospitals not covered by previous surveys for which no sources were known. At least some of these funds must come from public sources. If half are credited to government this is nearly one quarter of the wider estimate for public funded health R&D. (shown as "other public" in Figure 1.5)
>
> *Example iii).* In the *United States,* R&D funding/expenditure data for the Higher Education sector cover only separately budgeted R&D. The concept of GUF is not of use in this context. There are no estimates for "non-budgeted" health-related R&D.

Research and capacity building

Medical research councils and similar organisations have responsibilities for research training and capacity building as well as for funding /performing research projects. In countries such as Canada and the

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[13] How such data are collected is discussed in Chapter 3.

United Kingdom which collect Government Budget Appropriations or Outlays for some other S&T activities as well as R&D, such funding may be separated out and declared under another heading. In others, such as France, the funds of similar bodies (INSERM, CNRS) are 100% credited to R&D.

The sums involved are not very large compared to R&D funds proper. However, both the Canadian Medical Research Council and the English Department of Health see advantages in treating all their S&T funds as R&D support.

Breakdown of GBAORD between objectives

General approach

The GBAORD data are essentially political series and the classification of the funding of different programmes and institutions depends on how the government presents its R&D priorities as well as on the formal mandates of the institutions concerned. For example the whole of the National Institutes of Health is included in "health" in the United States, as is the Medical Research Council in the United Kingdom. In other countries, such as France, where there is a general research council, funds for very similar projects may be included in "advancement of research". In countries, which leave the higher education sector to carry out the national long-term research effort, the same project might be included in "General University Funds".

Effects of methods of breaking down GBAORD: core and peripheral funders

The breakdown is also affected by the way in which the data are actually collected or compiled. In Canada, France and the United Kingdom ministries and agencies are surveyed and are requested to break down their R&D funding between objectives. In other countries the body compiling GBAORD, usually an S&T ministry or agency, makes the breakdown for whole programmes or institutions. In the latter case the attribution will be more accurate if much of the S&T budget is already in detailed programmes (Austria, Germany, the Netherlands), than if the original break as reported to OECD is essentially for major institutions and programmes (Japan, United States).

A cross-classification of GBAORD between the national institutional categories and the health-related objectives may be revealing for those countries with more detailed methods of assembling the data. For example it is interesting to see whether all the R&D funding by the "core institutions" of the National Health Science and Innovation System is devoted to health-related objectives and, conversely, whether other "peripheral" institutions fund significant amounts of R&D with health as a primary objective.

Example i). Table 1.2 gives such a breakdown for *Canada*. It covers federal R&D funding as reported to OECD. It shows that about 20% of GBAORD for health as an SEO in 1997 did not come from health agencies. (A new agency dealing with all aspects of health R&D came into being at the beginning of April 2000.)

Table 1.2. **Canada: GBAORD for health as an SEO by agency, 1997**

	% of total health	Health as % of total
Medical Research Council	62.7	99.8
Health Canada	16.7	93.7
Natural Sciences and Engineering RC.	8.4	7.8
National Research Council	11.1	8.6
International Development Research Centre	1.0	7.6
Total Health as SEO	100.0	10.9

Source: Tables supplied by Statistics Canada.

Table 1.3. **France: Health -related funding in the BCRD, 1997**

Million FRF and percentages

	Health	Advancement of Research-Life Science	Other objectives	Total
		Million FRF		
Health agencies	2 996	174	224	3 394
Basic research institutions	874	3 070		3 944
Other agencies	718	598		
Total	4 588	3 842	224	8 654
		Percentages		
Health agencies	34.6	2.0	2.6	39.2
Basic research institutions	10.1	35.5		45.6
Other agencies	8.3	6.9		15.2
Total	53.0	44.4	2.6	100.0

Source: Ministère de l'Éducation nationale, DPD-C3.

> *Example ii*). Table 1.3 for *France* covers health R&D in the BCRD (civil R&D budget), which excludes most GUF. The left-hand categories are those of the national publication (basic research is an institutional category, not a function). The total is health-related R&D as defined for the national paper (health plus life sciences) plus any funding of other objectives by agencies included under health in the national institutional classification. It shows that virtually all the R&D by these agencies is for health plus life sciences but that 15% of the wider total comes from agencies which are not, at first sight, at the core of the National Health Science and Innovation System.

The GBAORD data are based on the primary objective of agencies, programmes or projects. They do not cover those undertaken for other purposes but which are health-related.

> *Example*. For the *United States,* the national health objective covers R&D funded by the Department of Health and Human Services of which by far the largest part is for the National Institutes of Health. When reporting to OECD the national objective Veteran Affairs is also included under health. The set of data compiled by the National Institutes of Health (Table 14.1) includes their estimates of health-related R&D in other departments and agencies. The table

> indicates that in 1997 such R&D funded by peripheral departments came to about 14% of their wider total, of which 7% by the Department of Defence, 2% by the Department of Energy and 1% by NASA. The National Science Foundation (in OECD advancement of research) funds less than 1% of the total. These "peripheral" funds are shown as "other Federal" in Figure 1.5.

Health R&D and basic research

Users of GBAORD data sometimes confuse *Advancement of research* as an SEO with *Basic research* as an activity. As a result they assume that Health as an SEO only covers applied research and experimental development. This is not so.

> *Example i).* In the *United States*, over half all federal R&D funding for the health objective is destined for basic research and the objective is responsible for almost half all federally funded basic research with only one quarter financed via advancement of knowledge (NSF, annual b).
>
> *Example ii).* In the *United Kingdom*, 62% of the funds of the Medical Research Council (wholly included in health as an SEO) are for basic research, all of it oriented basic research. (Department of Trade end Industry, etc., annual).

Summary and conclusions

GBAORD for the human health SEO gives an incomplete measure of government support for health-related R&D and the published data are not internationally comparable. The situation is somewhat better if funding of medical sciences (and possibly also biological sciences) via advancement of research and GUF are included. For countries with federal constitutions, state/provincial governments may contribute support to health-related R&D. The degree to which peripheral funding of health-related R&D is included varies depending on the method of compiling GBAORD.

Chapter 2

COMPILING PERFORMER-REPORTED HEALTH GERD

by

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General specification of GERD

The sum of spending on national territory as reported by performers is known as "Gross Domestic Expenditure on R&D", GERD. GERD is divided into four sectors of performance (Business Enterprise, Government, Higher Education and Private non-profit institutes (serving Households) and five sources of funds (the four plus "Abroad") for each sector. The *Frascati Manual* generally recommends an institutional classification for the sectors in which the unit making the return is classified according to its main economic or scientific activity and one or more functional classifications where each responding unit's R&D expenditure is broken down between different categories.

Health-related R&D in international sources

The current OECD R&D questionnaires does provide just enough information for one to be able to make one or more broad estimates of the level and performance structure of national health R&D expenditure and personnel (R&D in the pharmaceutical industry plus R&D in the medical sciences and/or for the health objective in the other sectors). Table 2.1 shows the data, which would be available from a full response, with Spain 1995 as the example. It is, in fact, the only country to provide such a complete set of relevant data. Table 2.2 shows which countries actually supply the series concerned.[14]

National estimates of health GERD

Countries compiling data on health-related R&D for national purposes need not be constrained by international classifications but can also take into consideration national specificities and institutional arrangements. National estimates of health GERD were provided by Australia (1992-93, 1994-95, and 1996-97 plus a later partial update for 1998-99),[15] Austria (1993), Canada (1970-98), Denmark (1991,

---

[14] The main OECD source of data is *Basic Science and Technology Statistics* (OECD, annual). This and other similar tables were based on the 1999 edition and thus the data as of November 1999. Some countries may collect and publish some of these series but not include them in their returns to OECD. Table 2.2 has been updated to January 2001 to reflect the latest state of reporting.

[15] Data for 1989-99 are used as far as possible for the comparisons in this chapter. Some breakdowns of the data, notably source of funds, are only available for 1996-97.

1993, 1995 and 1997), France (1997), Israel (1996), Norway (1997) and the United States (1995-98). An estimate of GNERD[16] based on independent funders' reports for 1998 was supplied for England. It has been adapted by the author to be roughly comparable with total GERD for 1997. Australia, Austria, Denmark, France and Norway also supplied R&D personnel data (see Chapters 5 to 14).

Table 2.1. **Spain: Categories of health-related R&D resources collected via the OECD and Eurostat surveys, example of a full return, 1995**

Expenditure in ESP millions, personnel in FTE

	First destination						
	Business Enterprise	Government	Higher Education	PNP	Total national territory	Abroad	**TOTAL**
a GBAORD							
objectives							
Health (OECD dest table*)	1200	17226	973	803	20202	30	**20832**
Health NABS (Eurostat)							**18434**
Medical GUF			16018		16018		**16018**
Medical non-oriented							**1727**
Industry - Drug							**398**
Industry -med inst.							**51**
	b Performing institutions						
Sources of funds	Drug industry		Medical sciences	Medical sciences			
Business Enterprise	29789		2021	423			
direct Government	787		8873	714			
GUF	0		10269	0			
Total public funds	787		19142	714			
Higher Education	0		4393	36			
PNP	0		193	511			
Abroad	784		171	69			
Total	**31359**		**27465**	**1752**			
Personnel							
Researchers	**1155**		**3934**	**291**			
Technicians	753		260	86			
Supporting Staff	915		665	47			
Total	**2822**		**4859**	**424**			
c Performer reported functions	Business Enterprise	Government	Higher Education	PNP	**Total**		
Expenditure							
Health as objective	31530	14485	20979	1330	**68325**		
Medecine as field	32135	19967	27465	1752	**81319**		
Personnel							
Medecine as field	2981	4103	4859	424	**12367**		

* Also includes ESP600 million for which no destination could be specified.

Source: OECD database November 1999 and Eurostat (annual).

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[16] GNERD covers R&D financed by a country. It includes payments to abroad and excludes R&D performed on national territory financed from abroad.

Table 2.2. **Summary of availability of health-related R&D expenditure data from the OECD R&D database as of February 2001**

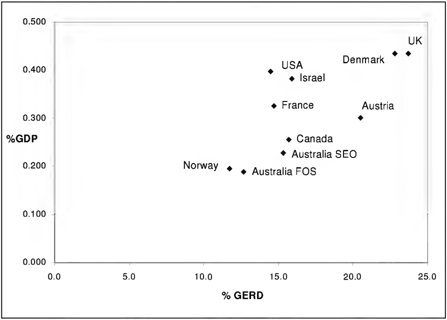
	Business enterprise	Government	Higher education	PNP
United States	Ph, PhS			
Japan	Ph, PhS	Hobj	Medsci, MedsciS	Hobj, Medsci, MedsciS
Germany	Ph, PhS	Medsci	Medsci, MedsciS[1]	-
France	Ph, PhS			
United Kingdom	Ph, PhS			
Korea	Ph, PhS, Hobj	Hobj	Hobj, Medsci, MedsciS	Hobj
Italy	Ph	Hobj[1]		-
Canada	Ph, PhS			
Netherlands	Ph	Hobj[1]	Hobj[1], Medsci	Hobj[1]
Australia	Ph, PhS, Hobj, Medsci	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS
Sweden	Ph, PhS	Hobj	Medsci, MedsciS	Hobj
Spain	Ph, PhS, Hobj, Medsci	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS
Switzerland	Hobj	Hobj		
Belgium	Ph		Medsci, MedsciS	Medsci, MedsciS
Austria	Ph, PhS	Hobj	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS
Finland			Medsci, MedsciS	Medsci
Denmark	Ph, PhS, Hobj	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS
Poland	Ph, PhS, Medsci	Medsci	Medsci, MedsciS	-
Mexico	Ph, PhS, Hobj	Hobj	Medsci, MedsciS	Medsci, MedsciS
Norway	Ph, PhS	Hobj	Hobj, Medsci, MedsciS	-
Turkey	Ph, PhS	Hobj	Medsci, MedsciS	-
Czech Republic	Ph, PhS, Hobj, Medsci	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci
Ireland	Ph, PhS	Hobj	Hobj, Medsci, MedsciS	Hobj
Portugal	Ph, PhS	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS
Hungary	Ph, Medsci	Medsci	Medsci, MedsciS	-
New Zealand	Ph			-
Greece	Ph			
Iceland	Ph, PhS, Hobj, Medsci	Hobj, Medsci	Hobj, Medsci, MedsciS	Hobj, Medsci, MedsciS

1. Last reported for 1991.
Ph: Total intramural R&D in the pharmaceutical industry.
PhS. Sources of funds R&D in the pharmaceutical industry.
Medsci. Total intramural R&D in the medical sciences.
MedsciS. Sources of funds R&D in the medical sciences.
Hobj. Intramural R&D for health as a socio-economic objective.
Source: OECD R&D database, January 2001.

These sets of data were compiled for national studies or simply for the informal workshop so too much should not be read into the international presentation in Figure 2.1. They are supplied to put the data in the discussions on differences in methods between countries that follow in perspective.[17] Most countries took a mixed approach, combining institutional and functional information to produce flow of funds charts and GERD tables. Australia made the most extensive use of detailed functional classifications providing two estimates; one based on its national classification by field of science and technology (FOS) and the other on its national classification by socio-economic objective. (SEO) The data for the United States are "lower limit". The estimate for the United Kingdom is particularly rough.

Figure 2.1. **National estimates of health-related GERD**

1997, 1998 or nearest year available



Source: National contributions and author's estimate (United Kingdom).

These national health estimates generally represented about 15% of total GERD rising to over 20% in Austria, Denmark and the United Kingdom. The funds represented more than 0.35% of GDP in Denmark, Israel, the United Kingdom and the United States.[18]

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[17] The four G7 countries, Canada, France, the United Kingdom and the United States do not supply enough data to OECD via the regular R&D survey to make estimates of apparent health GERD. The smaller Member countries who prepared national estimates of health-related GERD, Austria, Australia, Denmark and Norway, do supply such data to the OECD (see Table 2.2).

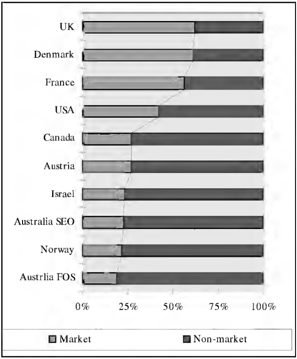
[18] GNERD figures based on funders reports give higher GDP percentages for the United Kingdom and the United States. In 1995, the National Institutes of Health figure for health GNERD mentioned in Chapter 14

For the purposes of the present study health GERD was divided into two major components, the market and non-market sectors. In general these correspond to the Business Enterprise (BE) sector and to the sum of the Government, Higher Education and PNP sectors, except where institutes serving enterprises are included in the latter. The market sector is the more important of the two in Denmark, the United Kingdom and France. In most of the others non-market performers carry out about three-quarters of all health-related R&D expenditures (Figure 2.2).

Cross-tables showing sources of funds and sector of performance for estimated Health GERD were supplied by Australia, (SEO and FOS 1996-97), Canada (1998), France (1997), Israel (1996) and Norway (1997) and one was estimated for the United Kingdom (1997) by the author. The Israeli categories do not match OECD sectors completely. Denmark, Israel and the United States did not supply full breaks by sources of funds. The estimate for the United States only distinguished between Federal government funds and all other sources. Denmark reported the difference between own funds and receipts from other institutions for the non-market sectors only. Israel only identified some categories of hospital funds.

Figure 2.2. **National estimates of health GERD in market and non-market sectors of performance**

1997-98 or nearest year available



Source: National contributions and author's estimate (United Kingdom).

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was USD 35.8 billion, or 0.5% of GDP. The English health-related GNERD in Chapter 13 came to GBP 4.9 billion for 1998-99, or 0.46 % GDP.

The two main components of the National Health Science and Innovation System (NHSIS) are largely independent in terms of R&D funds, as can be seen from Table 2.3. It shows that for the responding countries there was very little flow of funds from the non-market sectors to Business Enterprise for health R&D. The flows from enterprises to non-market performers were somewhat higher but never reached 10% of the estimated national total. These data are for flows within the country.

Table 2.3. **Flows between the market and non-market sectors as a percentage of estimated health GERD**

	To BE from non-market	To non-market from BE
Australia SEO 1996-97	2.0	7.6
Australia FOS 1996-97	1.0	8.2
Canada 1998[1]	0.2	6.3
France 1997	0.6	2.3
Norway 1997	1.1	2.6
United Kingdom 1997	0.6	1.9
United States 1998	0.1	..

1. Flows from BE to non-market excludes funding of some hospitals.

Source: National contributions and author's estimates (United Kingdom).

The market sector: Identifying and comparing health-related R&D in the Business Enterprise sector

Current reporting

International reporting

The classification list recommended in the *Frascati Manual* (based on ISIC Rev.3/NACE Rev.1) identifies the pharmaceutical industry and (optionally) medical appliances, instruments and control equipment, of which only part is health-related.[19] The OECD questionnaire requests data by the industry group of the enterprises but not by the product field of the R&D. The list specifies the pharmaceutical industry but groups the whole instruments industry. R&D data for the pharmaceutical industry as reported by OECD countries are currently available for most OECD countries (Table 2.2). OECD also maintains a special data base for total R&D expenditure in manufacturing and service industries entitled ANBERD where Secretariat estimates are made for missing data points including those for the pharmaceutical industry.

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[19] The structure of sub-classification of the industry differs between ISIC Rev.3 and NACE Rev.1 is as follows:

ISIC Rev 3		NACE rev 1
331 Medical appliances, instruments and control equipment	3311 Medical and surgical equipment and appliances	33.1
	3312 Measuring and testing equipment	33.2
	3313 Industrial process control equipment	33.3
332 Optical instruments and photographic equipment		33.4
333 Watches and clocks		33.5

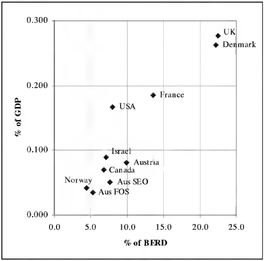
The OECD questionnaire also allows countries to report R&D expenditures in the BE sector for health as an objective and expenditure and personnel for medical sciences as a field of sciences. The response rates are low (Table 2.2).

The pharmaceutical R&D data are published in *Basic Science and Technology Statistics* (OECD annual a) and in the ANBERD publication. (OECD annual b). The objectives data are in all editions of *Basic Science and Technology Statistics* whereas the medical sciences data are only in the CD ROM version.

National estimates

For market performers, all countries included R&D in the pharmaceutical industry. Denmark, France and Norway also included the medical equipment industry. Austria, Norway and the United States included some elements of R&D by services. In the United States this was R&D by private medical practice and hospitals. In Austria and Norway it included R&D in institutes serving enterprises. The Australian coverage, based on SEO, is given in Table 2.6 below.

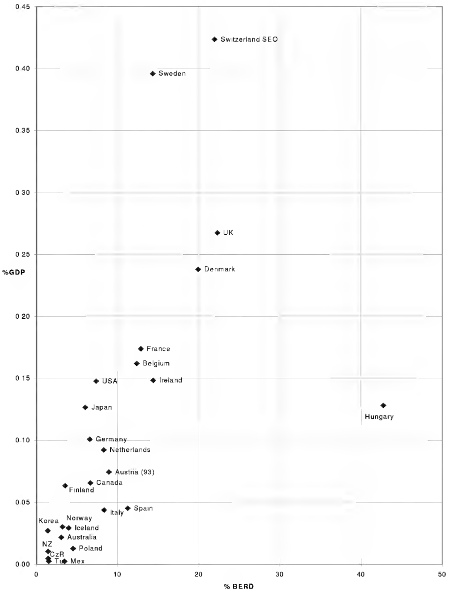
Figure 2.3 **National Estimates of Health R&D in the BE sector 1997, 1998 or nearest year available**



Source: National contributions and OECD, *Basic Science and Technology Statistics* 1999.

Figure 2.4. **R&D expenditure in the pharmaceutical industry**

1997 or nearest year available



Source: OECD R&D database, November 1999.

Figure 2.3 shows a comparison of the resulting data with GDP and with BERD. It indicates that health-related R&D spending is particularly high in Denmark and the United Kingdom with nearly one-quarter of BERD as against five to ten percent in most of the others.

R&D in the pharmaceutical industry

Most users of OECD data take R&D expenditure by the pharmaceutical industry as a proxy for total health R&D in the Business Enterprise sector, for example in *OECD Health Data 99* (see Chapter 4). Figure 2.4 shows the corresponding data as a percentage of BERD and GDP. (The point shown for Switzerland is for health as an SEO.)

Effect of including additional subcategories: medical instruments

R&D carried out by the pharmaceuticals industry is only one component of health-related R&D in the business sector. The other immediately identifiable manufacturing industry is medical instruments (ISIC 3311). Four of the participating countries included this industry in estimated health-related BERD. It was about 5% of the total in France, 10% in Australia and Denmark and over 15% in Norway (Table 2.4).

Table 2.4. **R&D in the medical instruments industry (ISIC 3311)**

1997 or nearest year available

	Australia 1996-97	Denmark	France	Norway
Million national currency	24	263	857	73.7
R&D in pharmaceutical industry = 100	19.8	9.9	6.0	22.3
% of estimated health BERD	9.3	10.1	5.5	16.2
% of total R&D in instruments industry	26.4	45.2	10.5	17.5

Source: National contributions and publications and OECD (annual a).

Refining the information for pharmaceuticals

Cross-classifications of BERD between industry groups and product fields[20] can reveal more information about health-related R&D in the sector, notably that undertaken outside the core industries. Table 2.5 shows such a comparison for Denmark for pharmaceuticals for 1995 and 1998.[21]

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[20] In the industry group approach, the R&D of each enterprise is allocated to the industry of its main economic activity (exceptionally R&D for a large enterprise with several distinct economic activities may be divided between them). In the product field approach, each enterprise is asked to break its R&D expenditure between the product fields involved regardless of its economic activities. The OECD does not request a breakdown by product field and it is only collected by some countries.

[21] This table could not be calculated for 1997 as there is less detail in the cross tabulation than in the earlier year.

Table 2.5. **Pharmaceutical R&D in Denmark: Industry group and product field, 1995 and 1998**

Percentage distribution

	R&D performed by the pharmaceutical industry by product field		R&D on pharmaceutical products by industry of performance	
	1995	1998	1995	1998
Manufacturing				
Pharmaceuticals	90.6	82.0	88.0	87.8
Other chemical-linked[1]	9.4	18.0	2.7	2.7
Other manufacturing	0.0	0.0	0.3	0.2
Non-manufacturing				
R&D services	..	..	5.9	6.2
Technical institutes	..	..	0.5	0.3
Other	..	..	2.2	3.1
TOTAL	100.0	100.0	100.0	100.0
Total million DKR	**2 132**	**3 584**	**2 196**	**3 346**

1. Other chemicals, rubber and plastics, food and drink.

Source: National industrial R&D surveys 1995 and 1998.

Australia does not find the product field approach useful but supplied a special set of data based on an extended definition of health as a SEO covering not only health proper but also the relevant industry subcategories of "industrial development" and some categories from "advancement of knowledge". The cross with industry of performance is shown in Table 2.6 (see also Chapter 5).

Table 2.6. **Australian Business Enterprise sector: R&D for human health as an SEO (extended coverage) by component and by performing industry, 1996-97**

Percentages

	Manufacturing				Services	Total
	Total	Drugs	Med. Inst.	Other		
Human pharmaceutical products	37.6	28.6	0.0	9.1	19.5	57.1
Health and medical adv. of knowledge	24.7	9.9	8.3	6.5	18.2	42.9
Total Health SEO (extended)	62.4	38.5	8.3	15.6	37.6	100.0

Source: Information supplied by Australian Bureau of Statistics after the Workshop.

Refining the measure of pharmaceutical R&D

Some R&D on pharmaceuticals will be undertaken in manufacturing firms for which this is not their main economic activity for example within a general chemical company.

> *Example i).* In *Denmark,* the industry also carried out the bulk of R&D on pharmaceuticals as a product field (88%) with only 3% undertaken in other manufacturing industries.

Example ii). In *Norway,* a comparison between industry group and product field shows no pharmaceutical R&D outside the chemical industries.

Example iii). In *Australia,* about 25% of all R&D in manufacturing industry on human pharmaceutical products (SEO) is performed outside the pharmaceutical industry.

In theory not all R&D by companies classified to the pharmaceutical industry may be for pharmaceutical products.

Example i). In *Denmark,* the pharmaceutical industry seems to be spreading its interests to associated products such as other chemicals, food and drink and rubber and plastics with the share of non-pharmaceutical R&D rising from 9% in 1995 to 18% in 1998.

Example ii). In *Australia,* over 20% of the R&D performed by the pharmaceutical industry is not for human health (widely defined) as an SEO.

Not all R&D in pharmaceutical firms is related to human health, some will be for agricultural pharmaceuticals.

Example. The *Pharmaceutical Research and Manufacturers of America* reported that 98% of their total company funding of intramural and extramural R&D on ethical pharmaceuticals at home and abroad was for "Human use" and under 2% was "Veterinary" (Table 3.1).

Identifying health-related R&D in the service industries

This falls into three main categories:

- R&D undertaken for health-related manufacturing industries by technical services industries, notably the R&D industry and the computer services industry.
- R&D undertaken for health service providers by technical services industries, notably the R&D industry and the computer services industry.
- R&D performed by market providers of health services.

The first two may be possible to track down via industry group/product field classifications or in the rare cases where firms are asked to break down their intramural R&D by SEO. The third is not specified in the current classification in the Frascati manual and the OECD R&D questionnaire. It would include private hospitals.

Example i). In *Denmark*, the service industries performed almost 10% of all R&D for pharmaceuticals as a product field in both 1995 and 1998 (see Table 2.5 above).

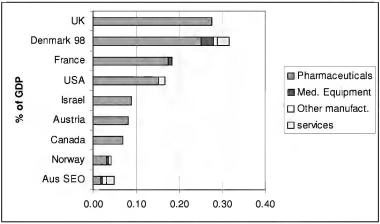
Example ii). In the *United States,* companies in the health services spent USD 1.2 billion on R&D in 1998, equivalent to almost 10% of company-funded intramural R&D funded in the pharmaceutical industry. This does not include R&D in commercial laboratories specialising in biological research (Table 14.2).

Example iii). In *Australia,* over one-third of all health-related R&D in the BE sector is performed by service industries (Table 2.6).

Figure 2.5 illustrates the importance of the differences discussed above for the countries where additional data is available. In Australia they have an important impact.

Figure 2.5. **Effect of including additional categories in health-related BERD**

1997 *or* 1998 *or* nearest year available



Note: Australia = 1996-97.
Source: National contributions and publications.

Comparing functional data with the core series for the pharmaceutical industry in international sources

Table 2.7. **Health-related R&D in the BE sector, various measures reported to the OECD**

	% BERD			% GDP		
	Health SEO	Medical sciences	Pharm industry	Health SEO	Medical sciences	Pharm industry
Australia simple 1996	2.5	4.3	2.9	.019	.033	.023
Czech Republic 1997		1.2	1.4		.009	.010
Hungary 1997		.6	42.7		.002	.128
Iceland 1997	20.5		4.0	.152		.009
Korea 1997	2.6		1.4	.051		.027
Mexico 1995	3.8		3.4	.002		.002
New Zealand 1997	6.8		1.5	.022		.005
Poland 1997		.6	4.5		.002	.013
Spain 1995	11.1	11.3	11.0	.043	.044	.043
Switzerland 1996	22.0			.424		

Source: OECD, *Basic Science and Technology Statistics* 1999 (OECD, annual a).

Table 2.7 compares various measures of health related R&D in the BE sector as reported to OECD, for those countries supplying health as an SEO or in the medical sciences.[22] In countries with low pharmaceutical R&D, the health SEO data can be significantly higher. The relationship between medical sciences, mainly available for Eastern European OECD countries, and the other two measures is not clear.

International reporting of sources of funds for health-related R&D in the market sector

Most of the countries which supply OECD with R&D data for the pharmaceutical industry give some information on the sources of funds. In general the industry finances nearly all the R&D it performs (see, for example, Table 2.1 for Spain). Similar information is not available from international sources for the medical instruments industry or for health-related R&D in the services.

The non-market sector: Identifying and comparing health-related R&D performed in the government, higher education and PNP sectors

Current international reporting

Data on health-related R&D in these three sectors are theoretically available from the OECD questionnaire both by field of science and by socio-economic objective. However, the amount of detail reported by countries varies considerably. Response from the G7 countries is particularly patchy (see Table 2.2).

The medical sciences

The *Frascati Manual* does not recommend an institutional classification for the government sector. It recommends that the main institutional classification for R&D in the Higher Education and PNP sectors should be into six major fields of science and technology (FOS): natural sciences, engineering, agricultural sciences *medical sciences,* social sciences, humanities. In this institutional approach, R&D should be allocated to a field at the level of the smallest homogeneous unit involved in one of the six one-digit fields for which a complete set of data can be obtained.

Medical sciences is defined as follows:

Medical sciences

Basic medicine (anatomy, cytology, physiology, genetics, pharmacy, pharmacology, toxicology, immunology and immunohaematology, clinical chemistry, clinical microbiology, pathology).

Clinical medicine (anaesthesiology, paediatrics, obstetrics and gynaecology, internal medicine, surgery, dentistry, neurology, psychiatry, radiology, therapeutics, otorhinolaryngology, ophthalmology).

Health sciences (public health services, social medicine, hygiene, nursing, epidemiology).

Source: Frascati Manual (OECD, 1994).

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[22] The SEO figure for New Zealand is taken from a national publication.

OECD collects R&D data for the Higher Education and Private non-profit sectors using the six fields identified above as the basic institutional classification. A full return for medical sciences would cover R&D expenditure broken down by type of cost and by source of funds and R&D personnel broken down by occupation and/or by level of qualification. The response to this part of the questionnaire is not very good with only seventeen OECD countries providing a return for the Higher Education sector with sources of funds for the medical sciences in the last exercise and even fewer for the PNP sector (Table 2.2). The data for the Higher Education sector are published in *Basic Science and Technology Statistics* (OECD, annual a). Those for the PNP sector can only be obtained by requesting a special extraction from the OECD database

Recent OECD questionnaires also request total R&D expenditure and personnel on the medical sciences in all sectors, including BE and government, to meet the needs of reporting via OECD to UNESCO. Response is as yet low, especially for government (Table 2.2) and comes mainly from recent OECD countries that previously used an UNESCO-based methodology. The data are published in the electronic but not the paper version of *Basic Science and Technology Statistics* (OECD, annual a).

Health as a socio-economic objective (SEO)

The OECD R&D questionnaire includes an optional table on the functional breakdown of the socio-economic objectives of intramural R&D as reported retrospectively by the performers grouped into the four standard sectors (Business Enterprise, Government, Private Non-Profit serving households and Higher Education). This topic is dealt with only briefly in the *Frascati Manual.* It is specified that "primary purpose" should be used rather than "content" and the minimum recommendation is that data should be collected for "defence" and for "control and care of the environment". The table in the questionnaire, however, specifies all twelve objectives as in GBAORD with the request that public GUF should not be grouped in advancement of knowledge but broken down according to the objectives for which it is spent. About half the OECD countries respond to this table for one or more non-market sectors (see Table 2.2). The data re published in *Basic Science and Technology Statistics* (OECD, annual a)

The national estimates of non-market health GERD

National specificities are particularly evident in the arrangements for non-market health R&D. National experts can mix and match institutional and functional data to reach a data set that they feel gives a reasonable picture of the level and structure of the R&D activities of their own National Health Science and Innovation Systems. Only Australia took a purely functional approach, providing series based on socio-economic objective and on field of S&T. Austria, Denmark, and to some extent Israel, also collected some project-level data in the non-market sector. Such detail was not available for Canada, France, the United Kingdom and the United States, which used semi-institutional approaches. R&D in the medical sciences were included for the university sector (incl. university hospitals). France and the United States also included some (United States) or all (France) other life sciences. The author's estimate for the United Kingdom is very rough.[23]

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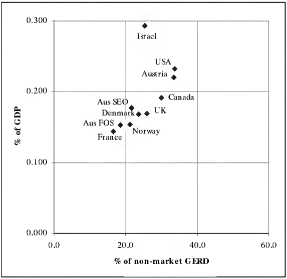
[23] The data for the government sector and for government-financed R&D in the Higher Education and PNP sectors are based on national survey results and have been reviewed and completed by the national authorities. The data for health-related R&D in the PNP sector and for such funds financed by non-government sources in the Higher Education sector are "guesstimates".

Figure 2.6. **National estimates of Health-related R&D in non-market sectors**

1997, 1998 or nearest year available



Source: National contributions and author's estimate (United Kingdom).

In most of the countries, health-related R&D represented 15-30% of total R&D in non-market sectors and 0.15-0.20% of GDP. The shares are higher in Israel, the United States and Austria.

Using the international data to identify health-related R&D

There is no single series which can act as a proxy for total health-related R&D in non-market sectors. Persons using OECD publications as a source of data on health-related R&D tend to use the expenditure data on "health" as an SEO with "medical sciences" as a field of science as a back-up for the non-market sectors of performance. (However if they also want a breakdown by source of funds then this is only available for the medical sciences in the Higher Education and PNP sectors). Figure 2.7 shows a mixed set of data derived from OECD sources. (The years are the latest for which data was available in *Basic Science and Technology Statistics* 1999, usually 1995.) The preferred method was health as an SEO in the government sector combined with medical sciences in the Higher Education and PNP sectors. There is a singular lack of points for G7 countries, with only Japan included. Sweden joins Austria and Denmark[24] as one of the apparent high funders of health-related R&D. There is clearly a group of countries which devote under 10% of non-market GERD and 0.1% of GDP to health/medical R&D who were not represented in the pilot study.

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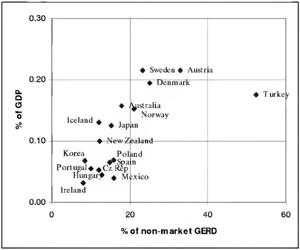
[24] The Danish data are for 1995. The reasons for the apparent decline in R&D in the Danish public health sector between 1995 and 1997 are discussed in Chapter 8.

Figure 2.7. **Apparent health-related R&D in the non-market sectors**



Source: OECD, *Basic Science and Technology Statistics 1999.*

Table 2.8 shows a comparison between data for health as an SEO and medicine as a FOST for those OECD countries that report both for at least one non-market sector.

At first sight one would expect spending on R&D for human health as an objective to be higher than R&D in the medical sciences as the former should also include health-related R&D in other fields of science. This is not always the case. Expenditure on R&D in the medical sciences is often higher than health as an objective in the Higher Education and PNP sectors. Not all R&D in the medical sciences may be credited to human health as an objective. As in the GBAORD series, some may be included in advancement of knowledge. There may also be R&D in the medical sciences for other mission-oriented objective such as defence.

We have two examples from the national studies, which throw some light on these differences.

Example i). Australia. The reason for the lower SEO data in responses to OECD is given in Table 2.9 which shows Australia "special" health as an objective taken from the national contribution paper rather than from the OECD R&D data-base. Here, as in Table 2.6, "health-related" covers not only health as a simple objective as reported to OECD but also the medical/health sciences component of advancement of knowledge and the R&D on health products from the industrial development SEO. Taken together these additional items represent about one fifth of the broader total. As might be expected, the effect of including the health-related component of advancement of knowledge is particularly important in the Higher Education sector. This wider SEO series is also almost 25% higher than spending on R&D in the medical sciences in government and PNP and almost 10% higher in the Higher Education sector.

Table 2.8. **Health as SEO and Medical sciences compared for R&D expenditures in non-market sectors in selected OECD countries**

	Government	Higher education	PNP	Total	Government	Higher education	PNP	Total
	% of R&D in each sector				% GDP			
Australia 1996: simple								
Health as objective	9.5	17.9	80.4	16.4	0.039	0.080	0.027	0.145
Medicine as field	9.1	21.3	71.0	17.6	0.037	0.095	0.024	0.156
Health as % med.sci.	*104.3*	*84.1*	*113.3*	*93.3*				
Australia 1996: special								
Health as objective	11.3	23.3	88.4	20.3	0.046	0.104	0.029	0.179
Medicine as field	9.1	21.3	71.0	17.6	0.037	0.095	0.024	0.156
Health as % med.sci.	*124.1*	*109.3*	*124.6*	*115.1*				
Austria 1993								
Health as objective	37.1	32.5	36.5	33.5	0.049	0.170	0.001	0.220
Medicine as field	36.4	31.7	36.6	32.7	0.048	0.165	0.001	0.215
Health as % med.sci.	*101.9*	*102.5*	*99.7*	*102.4*				
Denmark 1995								
Health as objective	34.2	13.1	64.0	22.8	0.106	0.059	0.013	0.178
Medicine as field		16.6	74.0			0.074	0.015	
Health as % med.sci.		*79.0*	*86.5*					
Iceland 1997								
Health as objective	4.5	13.1	48.7	9.8	0.025	0.068	0.012	0.104
Medicine as field	7.2	16.1	92.1	13.3	0.039	0.084	0.022	0.145
Health as % med.sci.	*62.5*	*81.4*	*52.8*	*71.9*				
Ireland 1994								
Health as objective	1.3	10.7	33.3	8.1	0.002	0.028	0.003	0.032
Medicine as field		10.5				0.027		
Health as % med.sci.		*102.0*						
Japan 1996								
Health as objective	4.3		7.1		0.011		0.010	
Medicine as field	4.2	25.3	6.2	15.3	0.011	0.106	0.008	0.125
Health as % med.sci.	*102.8*		*114.9*					
New Zealand 1997-98								
Health as output class	0.9	23.3		12.3	0.004	0.098		0.099
Medicine as field		23.4				0.096		
Health as % med.sci.		*99.8*						
Norway 1995								
Health objective current	11.4	16.9		14.7	0.034	0.075		0.109
Medical sciences: current	11.3	22.5		18.0	0.033	0.100		0.133
Health as % med.sci.	*101.0*	*75.2*		*81.7*				
Portugal 1995								
Health objective current	11.8	8.3	6.8	9.2	0.027	0.018	0.006	0.042
Medical sciences: current		8.5	10.3			0.018	0.009	
Health as % med.sci.		*96.8*	*66.1*					
Spain 1997								
Health as objective	17.2	10.8	36.2	13.6	0.026	0.031	0.003	0.060
Medicine as field	18.5	12.7	40.8	15.3	0.028	0.036	0.004	0.068
Health as % med.sci.	*93.3*	*85.1*	*88.8*	*88.7*				

Source: OECD, *Basic Science and Technology Statistics 1999* and national publications.

Table 2.9. **Australia: health-related R&D in the non-market sectors, 1996-97 by component SEO**

Percentages

	Government	PNP	Higher education	Total public
Health proper	21.5	14.9	44.6	81.0
Human pharmaceutical products	3.6	0.2	1.8	5.5
Medical in Adv. of knowledge	0.5	1.3	11.6	13.4
Total health-related	25.6	16.4	58.0	100.00
Where R&D in medical sciences =100	124.1	124.6	109.3	115.1

Source: Tables 5.7a and 5.18a.

Example ii). In *Austria*, overall spending on health as an objective was slightly higher than that on medical sciences in most sectors. The results of the 1993 survey show that the group of units included in the SEO health are not only engaged in R&D in the medical sciences. Of the 6% of their R&D expenditure not in medical sciences, 4.5% was in the natural sciences, 1.5% in the social sciences and 0.5% in the agricultural sciences.

International comparability of the underlying surveys

Effects of differing survey procedures between sectors within the "non-market sector"

Three sectors have been grouped here together as the "non-market" or "public sector" broadly defined as this is often how they are discussed in studies of national science and innovation systems. Furthermore, in the case of health-related R&D there are often very close links between institutions which are nominally in different sectors in terms of funding, personnel and place of work. The way these sectors are treated in national S&T statistics or indicator publications and in national surveys varies from country to country. The latter can affect whether a coherent approach to identifying health-related R&D is possible.

Example i). In *France,* the public sector as presented in national publications covers the Frascati government, Higher Education and PNP sectors. The health-related data are collected via three R&D surveys, one of government agencies, one of hospitals and centres involved in clinical research and one of (PNP) associations. Estimates are made for GUF.

Example ii). In *Norway*, the national science and innovation system has three main components, firms, institutes and universities. All "non-university institutes" are covered by a single R&D survey. They are subsequently divided between sectors when reporting to OECD. (Any PNP institutes serving households are included with government as performers).

Example iii). In *Australia*, the three sub-sectors are treated quite separately when reporting results. However the questionnaires used for the underlying surveys are very closely co-ordinated.

New and old institutes and foundations

Regular R&D surveys generally pick up health-related R&D funded or performed by long-standing research institutions such as the Ludwig Boltzmann institutes in Austria, the Pasteur and Curie institutes in

France or the Wellcome Foundation in the United Kingdom. Special steps may be needed to include newer foundations such as the Bill and Melinda Gates foundation.

R&D in the Higher Education sector

R&D in the higher education sector is extremely difficult to measure, as it is very closely associated with teaching and other activities. Methods used in OECD countries vary from detailed diary studies and full surveys at project level to the rough application of "R&D ratios" (e.g. medicine 33.33%) to data derived from university accounts as compiled by ministries of education. Thus the amount attributed to medical research may be the sum of spending on medical research projects or a more or less arbitrary share of the budgets of medical faculties. In general the greater the share of medical research which is financed by earmarked funds, for example by medical research councils, the more likely the data are to be accurate.

The *Frascati Manual* gives guidelines on the borderline between specialised healthcare and R&D as shown in Box 2.1. It is not clear whether the methods of collecting/estimating data for university or other hospitals allows this distinction to be made very accurately.

Box 2.1. **The borderline between specialised healthcare and R&D**

In university hospitals where, in addition to the primary activity of healthcare the training of medical students is of major importance, the activities of teaching, R&D and advanced as well as routine medical care are frequently very closely linked. "Specialised medical care" is an activity that is normally to be excluded from R&D. However, there may be an element of R&D in what is usually called "advanced medical care" carried out, for example, in university hospitals. It is difficult for university doctors and their assistants to define that part of their overall activities which is exclusively R&D. If however time and money spent on routine medical care are included in the R&D statistics, there will be an overestimate of R&D resources in the medical sciences.

Usually such advanced medical care is not considered R&D and all medical care not directly linked to a specific R&D project should be excluded from the R&D statistics.

Source: Frascati Manual (OECD, 1994).

Efforts to improve the general quality of these data would lead to better estimates of health-related R&D in this sector. (See for example, the Canadian experience described in Chapter 7.)

Identifying the sources of funds for health-related R&D in non-market sectors

International sources

It is possible to trace the sources of funds for R&D in the medical sciences in the PNP and higher education sectors for virtually all the countries for which total intramural R&D expenditures is reported for the field (Table 2.2). Source of funds data is not requested for the functional breakdown by SEO and probably would not be available from national surveys. It follows that there is no way from OECD sources of tracking the sources of funds for health-related R&D performed in the government sector.

Links between institutions

As well as straightforward flows of funds between institutions there may be more complex links between them in terms of personnel and of support via overheads, etc.

> *Example i).* In *France*, there were 7 790 R&D staff (FTE) employed by the "health" institutional category of the "public" sector in 1996, but 14 007 such persons actually working at these institutions (Table 17, national publication for R&D in the public sector 1999).
>
> *Example ii).* In *England*, spending on health-related R&D performed within the National Health Service (NHS) has cost implications for the service. A substantial proportion of the GBP 500 million R&D funding by the Department of Health/NHS in 1998-99 went to support costs for R&D funded by partner organisations: charities 26%; Medical Research Council 11%, universities 8%, other government department and the EU and the universities 4%.

Summary and conclusions

It is possible to derive a very broad estimate of health-related GERD for countries that make full responses to the OECD R&D questionnaire. It is not possible to identify sources of funds for lack of a suitable table for R&D performed in the government sector. The use of more detailed functional classifications would yield more internationally comparable data, particularly for the non-market sectors. However, the more detailed the data collected from performers, often the more difficult it is to trace back the funding to the original sources. This is, perhaps, not so important for international comparisons but if the same data-sets are to be useful for national studies and policy reports such links to funding agencies are essential. Furthermore, national and international data are difficult to interpret without some understanding of national health science and innovation systems.

Chapter 3

IMPROVING NATIONAL SURVEYS AND THEIR INTERNATIONAL COMPARABILITY: CLINICAL TRIALS AND R&D IN HOSPITALS

by

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Introduction

This chapter deals with two areas which national experts identified as particularly challenging. Both have consequences both for international methodology and for national practice. Both are affected by the way the National Health Science and Innovation System is organised, funded and regulated. The discussions at the Workshop only began to scratch the surface and further work will be needed to identify how both are treated in national R&D surveys before any recommendations can be made on best practice. Unless otherwise specified, all the examples are taken from the national papers contributed by participants or metadata supplied to OECD.

Clinical trials

Much of the following section is derived from the discussion paper prepared by Mireille Brochu and the present author for Statistics Canada for the informal workshop

Identifying the borderline of R&D

Before introduction onto the market new pharmaceuticals have to go through various stages of testing. The four stages in Canada and the United States are described in Annex 3.[25]

The cost of these clinical trials is very high. According to the Pharmaceutical Manufacturers of America, clinical evaluation in Phases I to III cost USD 4 billion in 1997, plus nearly USD 1 billion for Phase IV, giving a share of about one-third of company funded domestic US R&D on ethical pharmaceuticals (Table 3.1). Where the borderline is set between R&D and other innovation activities for these trials will have an important impact on the amount of health-related R&D funds, which are reported.

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[25] At the informal workshop, it was remarked that this model is no longer appropriate for new biotechnology products.

Table 3.1. **Domestic US R&D ethical pharmaceuticals, company financed, research-based pharmaceutical companies by function, main application and destination, 1997**

Function	USD million	Percentage share
Synthesis and extraction	1 816.0	11.8
Biological screening and pharmacological testing	2 294.3	14.9
Toxicology and safety testing	832.2	5.4
Pharmaceutical dosage formulation and stability testing	1 316.6	8.5
Clinical evaluation: Phases I, II and III.	4 094.3	26.5
Clinical evaluation Phase IV	894.1	5.8
Process development for manufacturing and quality control	1 454.2	10.0
Regulatory: IND and NDA	665.4	4.3
Bio-availability	322.6	2.1
Other	1 641.4	10.6
TOTAL	**15 422.0**	**100.0**
Human	15 142.7	98.2
Veterinary	279.3	1.8
Intramural	11 029.8	71.5
Extramural	4 392.2	28.5

Source: Pharmaceutical Research and Manufacturers of America Industry Profile 1999.

Clinical trials in the Manuals

The *Frascati Manual* (OECD, 1994) and the *Oslo Manual on Measuring Technological Innovation* (OECD/EUROSTAT, 1997) do not deal with clinical trials as a special category when discussing the borderline between R&D and other innovation activities. They are referred to in passing. Thus, in example a) in paragraph 80, the *Frascati Manual* states "Routine tests such as blood and bacteriological tests carried out for doctors are not R&D, but a special programme of blood tests in connection with the introduction of a new drug is R&D." Section 2.3.4 of the *Oslo Manual*, which deals with expenditure for tooling up, industrial engineering, industrial design, and production start up which is *not* R&D mentions both "expenditure for satisfying regulatory requirements: these may include drug registration, satisfying environmental regulations..." and "expenditure for testing technologically new or improved products or services". However, the latter entry specifies that testing of prototypes is R&D. Note that the example in the *Frascati Manual* has been there at least since the 1976 edition (where it illustrated "applied research"), well before the interest in describing all the stages of innovation.

Other views

> *Example i).* The *pharmaceutical industry* itself appears to include all clinical trials in R&D expenditure (see Table 3.1).
>
> *Example ii).* In *Canada*, there is a *tax credit scheme* for R&D which gives specific instruction on clinical trials (see Annex 3.2). It suggests that at least part of Phase IV trials are not eligible as R&D.
>
> *Example iii).* In *Israel*, the *Chief Scientist* at the *Health Ministry* was of the opinion that such clinical trials should not automatically be included in R&D.

Funding and performance of clinical trials

Phases II and III of clinical trials require volunteer patients. They are set up and carried out somewhere in the healthcare system. Traditionally this has been in university hospitals though there is evidence in the United States of increasing use of private doctors (*New York Times*, May 16 1999).

At first glance, most support for clinical trials will come from the pharmaceutical companies. However, there may be other sources. For example, in Canada and the United Kingdom, the Medical Research Councils fund some clinical trials. The performing units may pay some or all the costs, as is apparently the case in France.

The discussions at the informal Workshop revealed that there were different approaches to allocating the expenditure concerned to performers and to funders.

In theory, one can discuss whether the units that provide the patients and administer the drugs that are being tested are actually carrying out R&D themselves or are merely providing a technical service to researchers in the pharmaceutical industry. In the former case, there should be substantial extramural R&D payments by the industry and receipts by the units concerned. In the latter case, the expenditure would appear as the purchase of a service under "other current expenditures" in the intramural R&D of the companies. In practice, the matter is complicated by differing national regulations and by the fact that the drugs concerned may be provided free of charge to the health team concerned. According to the *Frascati Manual*, the cost of transfers in kind should be estimated.

> *Example i).* The Pharmaceutical Research and Manufacturers of America reported that in 1997 about 30% of its members' domestic R&D expenditure was outside the firm (see Table 3.1). It does not specify the destination of the funds.
>
> *Example ii).* In *France,* only a small flow of funds is registered as the pharmaceutical companies supply free materials for the trials and pay only the marginal costs of the performing hospitals and centres. The costs of the goods supplied are included in "other current costs" in the intramural R&D expenditures of the companies concerned.
>
> *Example iii).* In the *United States*, R&D expenditure in the Higher Education sector does not include clinical trials.

Measuring the resources devoted to R&D in hospitals

Establishing a good set of data on health-related R&D means having full and accurate coverage of R&D in hospitals. This poses a wide range of problems. The exchange of national experience at the workshop, based on a discussion paper by Susanne Sundnes (NIFU Norway), highlighted the following areas of concern.

Identifying and ear-marking the R&D content of "General Hospital Funds"

In a number of OECD countries, health ministries are showing increasing interest in identifying and earmarking funds for R&D rather than supporting it implicitly via "General Hospital Funds". This can lead to extended and improved surveys but also to problems if the sums ear-marked do not match survey results.

Example i). In *England*, a special survey was undertaken to determine the total net costs to all National Health Service (NHS) trusts of their involvement in R&D. This exercise was undertaken to allow a move in 1997-98 to contracting for R&D support on the basis of actual costs rather than the previously existing system of R&D subsidies paid to the trusts. The English Department of Health has recently announced plans to divide NHS funding into two distinct systems:

- NHS priorities and needs R&D funding.
- NHS support for science.

Example ii). In *France*, the survey of R&D in hospitals was begun following the introduction of a new Health Ministry programme funding clinical hospital research.

Example iii). In *Norway*, in the 1990s, university hospitals received a block grant from the Ministry of Health and Social Affairs to cover R&D, teaching medical students and advanced medical care. The survey agency estimated the R&D content using a combination of time-budgets, average salaries and other factors. In 1999, the ministry decided to earmark the R&D funds for the university hospitals and selected an amount much lower than that derived from these estimates probably because the ministry had only calculated the direct cost of research excluding various types of overheads and working hours of the staff concerned.

Including all hospitals especially non-university hospitals

The above-mentioned policy interest also strengthened the need to discover whether any R&D was being performed in non-university hospitals and to find appropriate methods of estimating the R&D expenditures concerned if they could only be surveyed in benchmark years.

Example i). In *Norway*, hospitals and clinics outside the universities are surveyed every ten years and estimates are made in the interim years.

Example ii). In *Austria*, there have been several not very successful efforts to measure R&D in hospitals other than university clinics. Estimates are included of 4% of the total budgets of the three hospitals hosting the university clinics and 1% of the budgets of other training hospitals. No estimates are made for the corresponding R&D personnel. Other hospitals are excluded.

Example iii). In *Denmark*, there is a full survey of R&D in hospitals every ten years, the last for 1997, using new methodology. In the interim years, estimates are made for the smaller hospitals. The final results of the detailed survey for 1997 yielded lower R&D figures than would have resulted from the estimation method.

Allocating hospitals and their funding sources to sectors

The OECD R&D questionnaire includes a table on the types of institutions included in each sector which specifies hospitals and clinics in the Higher Education sector. Response is very low. Similar institutional data on hospitals is not collected for the government and PNP sectors. Their treatment varies among countries.

Example i). In *Austria*, the university clinics are federal institutions, which are mainly financed by the Ministry of Science and also the Ministry of Health. They are included in the Higher Education sector. They are situated at or on the premises of hospitals, which are maintained by the *Länder* and which are included in the government sector.

Example ii). In the *United Kingdom*, all National Health Hospitals are included in the government sector.

Example iii). In the *United States*, R&D in hospitals owned, operated and controlled by universities and integrated operationally with the clinical programs of medical schools is included in the Higher Education sector. University-affiliated and other voluntary non-profit hospitals are generally included in the PNP sector. Any private hospitals surveyed are in the BE sector.

Example iv). In *Canada*, the coverage of health R&D performed in teaching hospitals was reviewed in 1999, as some such hospitals were fully or partially included in R&D in the Higher Education sector (HERD) and others were not. This review added the equivalent of 18% to health GERD. However, it was not possible to identify the sources of funds for this additional hospital R&D.

Dealing with multi-activity persons, etc.

Many hospital employees hold more than one position; full-time chief physician/part time-professor or other position combinations.

Example i). In *Norway*, a special survey of the university hospitals in 1996 showed that more than 50% of personnel performing R&D at hospital departments spend over 50 hours at work per week. This is far over the mean working time of 38 hours per week, and the implication is that R&D activities are partly conducted outside "normal" hours. According to the *Frascati Manual*, calculation of full time equivalent R&D personnel should be based on total working time, as one person can only represent one full-time equivalent. Thus "free time" R&D is also included in the Norwegian figures.

Example ii). In *France*, there is a special category of hospital staff who have multiple activities and who receive two salaries, one from the education ministry and another from the health ministry. The breakdown of their time and labour cost spent on health-related R&D is based on this salary break.

Direct and other costs of health-related R&D

Where R&D data are collected from hospitals, especially university hospitals, at department level the respondents may not be aware of the full cost of these activities or of all the sources of funds involved.

Example. In *Spain*, public sector hospital research is not organised centrally. There is a "research co-ordinator" but he or she only deals with monies from the major national health R&D fund. Such persons are not aware of the time spent on R&D financed from "General Hospital Funds" or direct support received at unit level from other sources, notably industry.

Detailed surveys: plans and publications

At the time of the workshop, Denmark had recently completed and published the results of a detailed survey of R&D in hospitals, and Austria awaited the health-related results of its detailed benchmark R&D survey. Iceland, Israel and Portugal were about to launch detailed surveys of R&D in hospitals. The draft Israeli questionnaire is included in Chapter 10.

A special topic group on measuring R&D in hospitals and clinical trials has been set up by the Working Party of National Experts on Science and Technology Indicators as part of the exercise to revise the *Frascati Manual.*

Chapter 4

OTHER VIEWS AND CLASSIFICATIONS OF HEALTH-RELATED R&D

by

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Consultant to Statistics Canada

Introduction

This chapter deals with health-related R&D data from two different frameworks, OECD Health Accounts and the associated data collection exercises and a series of special efforts to assemble data on health-related R&D as reported by funders, first by the National Institutes of Health (United States) and subsequently by the Global Forum for Health Research.

R&D in OECD Health Accounts and the OECD Health Data publication

Introduction

> The need for internationally comparable data is on the rise as national administrations seek to evaluate their healthcare systems against those of other countries.
>
> *Source*: OECD *Health Data 99.*

OECD has been active in uniform reporting on healthcare systems since the mid-1970s. Over the years, harmonisation of concepts and definitions went hand in hand with the annual data collection by the OECD Secretariat of health and healthcare statistics.

In more recent years, the activities of data collection/publication and the codification of methodology have developed considerably. The data collection has been put on a more formal footing and an *ad hoc* group of experts to act as national correspondents has been set up. The Health Accounts have been developed by another expert group and are currently being pilot tested. This work is undertaken in the Health Policy Unit of the Social Policy Division of the OECD's Directorate for Education, Employment, Labour and Social Affairs (DEELSA). It reports to the OECD Committee on Social Affairs.

R&D as a health-related function in the Health Accounts

The provision of healthcare and its funding is a complex, multidimensional process. The set of Core Tables in the System of Health Accounts (SHA) (OECD, 2000) addresses three basic questions:

- Where does the money come from? (Source of funding)?

- Where does the money go to? (Provider of healthcare services and goods)?
- What kind of (functionally-defined) services are performed and what type of goods are purchased?

Consequently, the SHA is organised around a tri-axial system for the recording of health expenditure by means of a newly proposed International Classification of Health Accounts (ICHA) defining:

- Healthcare by function (ICHA-HC).
- Healthcare service provider industries (ICHA-HP).
- Sources of funding for healthcare (ICHA-HF).

R&D is treated under the listing of Healthcare by function but only as a "further health-related function" which is not included in the body of the accounts but as an additional memorandum item. "Health-related functions should be distinguished from the core of healthcare functions. They can be very closely linked to healthcare in terms of operations, institutions and personnel, but should, as far as possible, be excluded when measuring activities belonging to core healthcare functions".

Table 4.1. **R&D in the OECD Health Accounts: Healthcare services and goods**

Expenditure by function

			Source of funding		
Code	Functions	Total	HF.1 General govern-ment	HF.2 Private sector	HF.3 Rest of the World
	Health functions				
HC.1-HC.2	Services of curative and rehabilitative care				
HC.3	Services of long-term nursing care				
HC.4	Ancillary services to healthcare				
HC 5	Medical good dispensed to outpatients				
HC.5.1	Pharmaceuticals and other medical non-durables				
HC.5.2	Therap. appliances and other medical durables				
HC.1-HC.5	Personal medical services and goods				
HC 6	Prevention and public health services				
HC.7	Health programmes administration and health insurance				
HC.1-HC.7	Total current expenditure on health				
HC.R.1	Gross capital formation				
	Total expenditure on health				
	Memorandum items: Further health-related functions				
HC R.2	Education and training of health personnel				
HC.R.3	Research and development in health				
HC.R.4	Food hygiene and water control				
HC.R.5	Environmental health				
HC.R6	Administration and provision of social services in kind to assist living with disease and impairment				
HC.R7	Administration and provision of health -related cash benefits				

Source: A System of Health Accounts, Table 5.

In the tables to the accounts, R&D appears only crossed with the source of funds classification as summarised in Table 4.1. The further breakdown of R&D as a function by source of funds is as in Table 4.2. Health expenditure by function is not crossed with healthcare providers as shown in Figure 4.1.

Table 4.2. **Sources of funding categories (further detail)**

General government	HF.1	Private sector	HF.2	Rest of the world	HF.3
General government (except social security)	HF.1.1	Private social insurance	HF.2.1		
Social security funds	HF.1.2	Other private insurance	HF.2.2		
		Private household out of pocket expenses	HF.2.3		
		NPIs serving households (excl. insurance)	HF.2.4		
		Corporations (excl. health insurance)	HF.2.5		

Source: A System of Health Accounts, Table 5.

This set of tables is currently being pilot tested in a number of OECD countries. There also some effects on the tables already collected for the OECD compendium of health data.

Maximum use has been made of the *Frascati Manual* for the guidelines on health-related R&D. However, these data will be based on national accounts definitions of expenditures rather than *Frascati* ones. Furthermore, the SNA treats private sector R&D as intermediate consumption. As admitted above, there will be problems of overlaps between R&D as a supplementary function and other health functions, notably medical care, and also between R&D and other supplementary functions, notably higher education. The *Frascati Manual* also recognises the problem of measuring industrial R&D expenditure where there is not a separate R&D establishment.

The R&D tables in "OECD Health Data 99"

The OECD has been publishing health statistics since the mid-1980s. The first edition of the *OECD Health Data* publication was issued in 1991. The 1999 version of the information system includes some 1 000 series selected because they were relevant to the description of key aspects of healthcare systems, sufficiently consistent to enable cross country comparisons and available in a significant number of countries. Data for some established series go back to the early 1960s. Although many variables do not match all three criteria, they are included to encourage greater conceptual convergence between OECD countries.

R&D is treated in the chapter on health-related functions in the *Expenditure on Health* section. This is a new chapter in the 1999 questionnaire, regrouping variables which had been previously been treated elsewhere, presumably to reflect the treatment in the new Health Accounts.

Four variables deal with R&D expenditure. These fall into two categories.

***Those which are still derived from the OECD R&D database*:**

- BUDG – Central government budget on health R&D. (GBAORD for health as an SEO)

- PHTO – Expenditure on pharmaceutical industry R&D.

Those that were originally derived from the R&D database but have since been updated on a different basis:

- DRPU – Public expenditure on health R&D.
- DRTO – Total expenditure on health R&D.

RSDV: Expenditure on health-related functions

FORM – Expenditure on health education and training.

DRTO – Total expenditure on health R&D.

PHTO – Expenditure on pharmaceutical industry R&D.

COHY – Expenditure on food, hygiene and drinking water control.

SAEN – Expenditure on environmental health.

DRPU – Public expenditure on health R&D.

BUDG – Central government budget on health R&D.

Source: OECD Health Data 99.

The availability of data is shown in Table 4.3. For the second category, it is indicated whether the data come from/are compatible with STI data or whether they come from different national sources. The guidelines are attached as Annex 4.

Special health R&D surveys: National Institutes of Health and the Global Forum

Introduction

This section deals with two special efforts to compile internationally comparable data on health R&D. While designed to answer rather different questions, they use the same basic methodology of compiling data reported by R&D funders. The first, undertaken by the National Institutes of Health in the United States, ended round about 1990. The second then picked up the results and developed them to examine the share of health R&D which was relevant to the problems of developing countries. This second project is still running and aims to set up an international database with wider applications.

National Institutes of Health

The Fogarty International Center for Advanced Study in the Health Sciences of the National Institutes of Health has as its mission the fostering of international co-operation and collaboration through its scientific research programmes the promotion of scientific exchange between United States and foreign scientists and the co-ordination of NIH activities concerned with health sciences at the international level. During the 1970s and 1980s, the Centre financed three consecutive efforts to advance the collection of internationally comparable data on funding of biomedical and later of all health research.[26] These involved trying to assemble data sets reported by the funders using the same classifications and definitions as the National Institutes of Health. These exercises did spur a number of individual countries to undertake studies of health R&D notably the German report (Statistiches Bundesamt, 1992) which was influential at the time of the last revision of the *Frascati Manual.* However the Fogarty Center failed to hold a planned major conference at the end of the 1980s and did not continue the project. The final report (Fogarty Int. Center, 1990) is a mine of information on data collection practice at that date.

Table 4.3. **Availability of data on the four R&D expenditure tables in *OECD Health Data 99***

	Central government budgets	Pharmaceuticals	Public R&D expenditure		Total R&D expenditure	
Australia	X	X	X	SEO	X	SEO
Austria	X	X	X	SEO	X	
Belgium	X	X	X		0	
Canada	X	X	X	National	X	National
Czech Republic	X	X				
Denmark	X	X	X	National	X	SEO
Finland	X	X	0			
France	X	X	X	National	X	National
Germany	X	X	X	National	X	National
Greece	X	X	0			
Hungary	X		X			
Iceland	X	X	X		X	
Ireland	X	X	0	SEO	X	SEO
Italy	X	X	0	SEO	0	SEO
Japan	X	X	X	National	X	National
Korea	X	X	X	National	X	National
Luxembourg						
Mexico	X				X	
Netherlands	X	X	X	SEO	X	SEO
New Zealand	X	X	X	National	X	National
Norway	X	X	X	SEO	X	National
Poland						
Portugal	X	X	0	SEO	X	SEO
Spain	X	X	X	SEO	X	SEO
Sweden	X	X	X	National	X	SEO
Switzerland	0		X	National	0	national
Turkey		X	X		X	
U.K.	X	X	0		0	
U.S.A	X	X	X	National	X	National

X: Reasonable series.
O: Occasional data points.
SEO: Health as a socio-economic objective of performance.
National: Series provided by national correspondents.

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[26] Including OECD/STIU (1981) and Durch *et al.* (1986).

R&D and the disease burden

Just as the Fogarty Centre was abandoning its efforts to measure health R&D, a new exercise was launched in 1988 by the Centre of Population Studies of Harvard University, notably by Dr. Catherine Michaud and Professor Christopher Murray. They profited from the material and documents from the Fogarty Centre and adopted essentially the same approach of collecting *funder-reported* data but with the aim of estimating a world total. The focus here is on R&D as a means of improving the health of populations.

R&D and the burden of disease

If anything leaps out at once from the figures, it is that investment for research and development relevant to the diseases and conditions that burden the low-income and middle-income countries occupies a remarkably low priority in worldwide spending on health R&D.

Source: Michaud and Murray, 1996.

Dr Michaud's efforts to measure and analyse this imbalance in health R&D funding (known as the "10/90 problem") have gone through various stages and are still in progress[27]. The institutional arrangements for funding this work have changed somewhat over time and the policy framework has developed.[28] This framework is particularly interesting including, for example, a classification of the "possible outcomes", *i.e.* products and processes resulting from health-related R&D. However, some of the basic categories are defined in ways which give a wider coverage to health R&D than the *Frascati Manual*, notably re capacity building.

All quantitative efforts have involved compiling world totals for health related R&D funding using the regular OECD/Eurostat/UNESCO publications and associated national publications; direct informal collection and plausible estimations. Special estimates are made to relate these R&D funds to the disease burden in developed and developing countries.

Monitoring resource flows for global health R&D: the plan

The work is currently undertaken for the *Global Forum for Health Research* which is an international foundation whose central objective is to help correct the 10/90 disequilibrium and focus research efforts on the health problems of the poor by reallocating research funds and by facilitating collaboration amongst partners. It brings together a wide range of partners, including government policy makers, multilateral organisations bilateral aid donors, international foundations, national and international NGOs, women's organisations, research-oriented bodies and private sector bodies. Its analytical work concentrates on: methodologies for priority setting; burden of disease and health determinants; cost-effectiveness analyses and analysis of resource flows and monitoring progress in correcting the 10/90 gap.

The ongoing project on *monitoring resource flows for global health R&D* was launched with a large meeting in March 1998 of a wide range of interested parties representing both demand for data and potential sources of supply, convened jointly by the Global Forum and the World Health Organisation.

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[27] See Murray *et al.* (1990), Michaud and Murray (1993) and Michaud and Murray (1996).

[28] See Commission on Health Research for Development (1990), and Task Force on Health Research for Development (1991). A summary is given in "Complementary Approaches for Priority Setting in Health Research: Review and Perspectives", Chapter 2 of Global Forum for Health Research (2000).

Both the Directorate of Science, Technology and Industry and the Health Unit of the Directorate for Education, Employment. Labour and Social Affairs of OECD were invited and the author attended on behalf of OECD. Following this, a Core Group was set up of persons to collaborate in developing a systematic mechanism for monitoring resource flows. It does not include any national agencies represented on the Working Party of National Experts on Science and Technology Indicators or involved in OECD Health Accounts and Statistics. After leaving OECD, the author attended Core Group meetings as an informal expert.[29]

The ultimate aim is to set up a new database on health R&D, possibly at WHO, based on the funding approach for use by decision makers in the following key institutions:

- Ministries of health and public health agencies.
- WHO and other UN agencies.
- Development banks.
- Bilateral organisations.
- Foundations and other non-profit organisations.
- Private-sector companies.

The monitoring project originally had four components: a special on-line survey of the main health R&D funding agencies in developed countries; an effort to establish total public (non-market) funded health related R&D in developed countries; estimates of total funding by the pharmaceutical industry (industry sources) by type and orientation; and the organisation of a set of surveys of health-related R&D in developing countries.

The most ambitious component is the special on-line survey which is specially designed to collect data on health-related R&D. The long-form questionnaire covers total health related R&D funding by each agency broken down by source of funds and by destination. Health-related R&D covers both R&D programmes and projects and capacity building as shown in Table 4.3. The link to the disease burden is shown in Annex 5. The long form also requests an experimental breakdown of funding by expected outcomes of the R&D funded using the classification in Table 4.4. A short-form questionnaire asking for much less information was used as an initial step.

Current state of play

An interim report was made to the International Conference on Health Research for Development hosted by the World Health Organisation, the World Bank, the Council for Health Research in Development and the Global Forum for Health Research in Bangkok in October 2000.

For the *special survey*, the 100 top health R&D funding agencies in OECD countries were contacted. So far response has been disappointing, giving only enough material for illustrations.

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[29] An observer from the Biotechnology Unit of the Directorate for Science, Technology and Industry currently represents the OECD.

Table 4.4. **Categories of health-related R&D funding in the Global Forum survey**

1.	**HEALTH R&D PROGRAMMES AND PROJECTS**
1.1	FUNDAMENTAL RESEARCH (not elsewhere classified)
1.2	HEALTH CONDITIONS (R&D on major disease groups)
1.2.1	GROUP I (Communicable, maternal, perinatal and nutritional conditions)
1.2.2	GROUP II (Non-communicable diseases)
1.2.3	GROUP III (Injuries)
1.3	RISK FACTORS
1.3.1	Proximate: smoking, diet, alcohol, job, illicit drugs
1.3.2	Distal: poverty, inequality, agriculture practices, education, natural disasters, food safety
1.4	RESEARCH ON HEALTH SYSTEMS
1.4.1	Policy
1.4.2	Health Services
1.4.3	Intelligence
2.	**CAPACITY BUILDING**
2.1.	HUMAN CAPACITY BUILDING (training of researchers and research staff)
2.1.1	Academic degrees:
	PhD
	Graduate, non PhD
2.1.2	Short-term courses
2.1.3	Seminars/workshops
2.1.4	Networks of people
2.2	INSTITUTIONAL CAPACITY BUILDING
2.2.1	Equipment
2.2.2	Buildings
2.2.3	Development of management systems
2.2.4	Electronics and infrastructure networks

Source: The *10/90 Report on Health Research 2000* and draft template.

Table 4.5. **Experimental classification of health R&D outcomes in the Global Forum survey**

	Overall inputs by anticipated outcome of R&D
1.	**Products**
	Drugs
	Vaccines
	New diagnostics
	New prosthetic devices
	Equipment, including tools for public health
	Other
2.	**Non-product interventions**
3.	**Instruments of policy**
	Pricing and taxing policies
	Pricing policies for health services
	Essential drugs list
	Policies for paying health workers
	Other

Source: The *10/90 Report on Health Research 2000* and draft template.

Data on total public health-related R&D funding were compiled from OECD sources and national publications. The aim was to reach a total for such funding in the OECD area for comparison with the estimated amount of health R&D in developing countries and to act as background of the discussion of R&D for developing countries. The preferred data set covers funders' reports of GBAORD for health, medical sciences in advancement of research and GUF and industrial development as described in Chapter 1, plus data or estimates for similar funding by state/provincial government. Where suitable funding data was not available, performer-reported data on government-financed R&D for the health SEO (government) and in the medical sciences (Higher Education and PNP) were used. The resulting estimates probably yield a plausible OECD total but are not internationally comparable between countries.

The exercise on health-related R&D in developing countries turned up a substantial amount of material, drawing in special surveys in Malaysia, the Philippines and Thailand,[30] the RYCIT[31] S&T indicator reports and other national studies. A special study was undertaken of funding of capacity building for health-related research, using data from a wide range of donor agencies.

The conference provided an opportunity for interested parties to review available information and to discuss the current status of the project and potential future steps. As a result, the partners involved in the initiative decide to:

- Continue with the RF Core Group discussion to define possible strategies for data collection.
- Discuss the use of the information.
- Review the data-collection mechanisms.

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[30] See Alano and Almaria (2000). Part 2 of this report includes a manual on tracking country resource flows for health research and development designed to allow other countries wishing to make similar studies to profit from the lessons learnt by the three countries.

[31] Red Iberoamerican de Indicatores de Cienca y Tecnologia.

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Annex 1

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Annex 2

HEALTH-RELATED R&D IN THE EUROSTAT NABS 1993 CLASSIFICATION

Chapter 4. Protection and improvement of human health (Eurostat, 1994)

This chapter covers research aimed at protecting, promoting and restoring human health broadly interpreted to include health aspects of nutrition and food hygiene. It ranges from preventive medicine, including all aspects of medical and surgical treatment, both for individuals and groups, and the provision of hospital and home care, to social medicine and paediatric and geriatric research.

General research

This heading covers research work of a manifestly general character and research relating to more than one of the other headings in this chapter but which cannot be divided.

Medical research, hospital treatment, surgery

This heading covers research work on the development of early diagnosis (screening and preventive medicine), confirmation of diagnoses and development of treatment for various syndromes. It also includes:

- Scientific research on specific diseases – cancer, cardiovascular diseases, infectious diseases, kidney diseases, tropical diseases, social diseases, psychiatric diseases, etc.
- Research on transplants, organ banks, grafting, etc.
- Research on the development of clinical medicine and hospital treatment, e.g. new methods of anaesthesia, intensive care, monitoring, resuscitation and special treatments, including radiation treatment, surgery of all types, obstetrics and related disciplines.

Paediatric and geriatric research is also included under this heading unless it is in the field of preventive medicine.

Not included: medical research into occupational/industrial accidents.

Preventive medicine

This heading covers research into the prevention of disease for all population groups. This includes, in particular:

- Preventive epidemiological research concerning gerontology and geriatrics.
- Research on general prophylaxis and vaccination techniques.
- Research on early diagnosis and prevention of medical conditions peculiar to new-born babies, children and the elderly.

Biomedical engineering and medicines

This heading covers research in the field of development, testing, adaptation and use of medicines, vaccines, serums, prostheses and medical apparatus. It covers the entire field of biomedical engineering and its related development work. It also includes:

- Research on the pharmacological effectiveness and safety of medicines, vaccines, serums antibiotics and anti-viral agents.
- Research on the synergy and interaction of medicines.
- Pharmacodynamics.
- Biological research on the diagnosis and treatment of pathological diseases.

Not included: The production of pharmaceutical products.

Occupational medicine

This heading covers research into occupational diseases and industrial accidents, and pollution at the place of work.

Not included:

- Research on the improvement of the health of society as a whole (by the identification, treatment and prevention of disease).
- Research on the prevention of occupational diseases.

Nutrition and food hygiene

This heading covers research into the relationship between nutrition and health as well as the effect on health of all kinds of chemicals, micro-organisms, parasites and toxic products. This includes, in particular:

- Research on human nutrition (dietetics for the healthy).
- Research on nutritional hygiene, aimed at the safety of foodstuffs.
- Research aimed at combating all toxic and carcinogenic elements in foodstuffs.
- Maintaining the food chain and the development of new food-stuffs for mankind.
- Research aimed at combating food adulteration.

Not included: Research aimed at the improvement of food quality from the point of view of its nutritional effect.

Drug abuse and addiction

This heading covers research into reducing the risks of addiction as well as research bearing on the analysis and treatment of self-intoxication caused by foods, tobacco, alcohol, drugs and the abuse of certain medicines.

Social medicine

This heading covers research into public health and the medical care of the communities from an organisational and socio-medical point of view.

Hospital structure and organisation off medical care

This heading covers research aimed at the improvement of the structure of health services within the framework of hospitals or the community. It includes, in particular:

- Research on the efficiency and cost-effectiveness of healthcare institutions, e.g. their planning, regional distribution, organisation management and administration.
- Research related to the improvement of after-care, emergency treatment and home care.

Research into the structure of healthcare and the regulation of public health, as far as it concerns function and performance.

Other medical research

(no guidelines supplied)

Chapter 10. Research financed from GUF and Chapter 11. Non-oriented research

10.6 and 11.6 Medical sciences

Anatomy, cytology, physiology, genetics, pharmacy, pharmacology, toxicology, immunology, and immuno-haematology, clinical chemistry, clinical microbiology, pathology, anaesthesiology, paediatrics, obstetrics, and gynaecology, internal medicine, surgery, dentistry, neurology, psychiatry, radiology, therapeutics, otorhinolaryngology, ophthalmology, public health services, social medicine, hygiene, nursing, epidemiology.

10.3 and 11.3 Biological Sciences

Biology, botany, bacteriology, zoology, entomology, genetics, biochemistry, biophysics, microbiology, other allied sciences excluding clinical and veterinary sciences.

Annex 3

CLINICAL TRIALS

A4.1. Phases of product development in the United States

(From Alliance Pharmaceutical Corporation Web-site)

It takes 12 years on average for an experimental drug to travel from lab to medicine chest. Only five in 5 000 compounds that enter pre-clinical testing make it to human testing. One of these five tested in people is approved.

	Pre-clinical Testing		Phase I	Phase II	Phase III		FDA		Phase IV
Years	3.5		1	2	3		2.5	12 total	
Test population	Laboratory and animal studies	File IND at FDA	20 to 80 healthy volunteers	100 to 300 patient volunteers	1 000 to 3 000 patient volunteers	File NDA at FDA	Review process/ approval		Additional post marketing testing required by FDA
Purpose	Assess safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side-effects	Verify effectiveness, monitor adverse reactions from long-term use				
Success rate	5 000 compounds evaluated		5 enter trials				1 approved		

Source: Dale E. Wierenga, Ph.D. and C. Robert Eaton, Office of Research and Development, Pharmaceutical Manufacturers Association.

In reviewing this report, it is important to keep in mind the realities of the drug discovery and development process. The US system of new drug approvals is perhaps the most rigorous in the world. On average, it costs a company USD 359 million to get one new medicine from the laboratory to the pharmacist's shelf, according to a February 1993 report by the Congressional Office of Technology Assessment (OTA, 1993).

Assessment

The flow chart accompanying this article gives the success rate of drugs and the length of time each step takes. Overall, about one in five of the medicines that begins clinical testing makes it through the trials and the approval process.

New medicines are developed as follows:

Pre-clinical testing. A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests take approximately three and one-half years.

Investigational New Drug Application (IND). After completing preclinical testing, the company files an IND with FDA to begins to test the drug in people. The IND becomes effective if FDA does not disapprove it within 30 days. The IND shows results of previous experiments, how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. In addition, the IND must be reviewed and approved by the Institutional Review Board where the studies will be conducted, and progress reports on clinical trials must be submitted at least annually to FDA.

Clinical trials, Phase I. These tests take about a year and involve about 20 to 80 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolised and excreted, and the duration of its action.

Clinical trials, Phase II. In this phase, controlled studies of approximately 100 to 300 volunteer patients (people with the disease) assess the drug's effectiveness and take about two years.

Clinical trials, Phase III. This phase lasts about three years and usually involves 1 000 to 3 000 patients in clinics and hospitals. Physicians monitor patients closely to determine efficacy and identify adverse reactions.

New Drug Application (NDA). Following the completion of all three phases of clinical trials, the company analyses all of the data and files an NDA with FDA if the data successfully demonstrate safety and effectiveness. The NDA must contain all of the scientific information that the company has gathered. NDAs typically run to 100 000 pages or more. By law, FDA is allowed six months to review an NDA. In almost all cases, the period between the first submission of an NDA and final FDA approval exceeds that limit; the average NDA review time for new molecular entities approved in 1992 was 29.9 months.

Approval. Once FDA approves the NDA, the new medicine becomes available for physicians to prescribe. The company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional studies (Phase IV) to evaluate long-term effects. Discovering and developing safe and effective new medicines is a long, difficult and expensive process. The research-based pharmaceutical industry will invest USD 12.6 billion in research and development this year, and that investment has been doubling every five years.
Source: Alliance Pharmaceutical Corp. *http://www.allp.com/drug_dev.htm*

A4.2. Revenue Canada's guidelines on the eligibility of clinical trials in the pharmaceutical industry introduction

This document is to serve as a guideline for use in the review of clinical research with emphasis on clinical trials undertaken to meet the regulatory requirements of the Health Protection Branch (HPB) of Health Canada. The document should assist in determining those aspects of clinical research that are eligible as Scientific Research & Experimental Development (SR&ED) under subsection 2900(1) of the Income Tax Regulations (the "Regulations").

Stages of clinical research

Clinical research undertaken to meet regulatory requirements for HPB approval is comprised of the following:

Phase I. Human safety trials.

Phase II. Early efficacy trials.

Phase III. Expanded therapeutic trials.

Phase IV. Post-approval or general usage trials.

Before clinical research begins, the drug developer must obtain clearance from the HPB of Health Canada. The clearance is based on the review of a Preclinical New Drug Submission (PNDS) also called Investigational New Drug Submission (IND). The PNDS discloses preclinical research information, available clinical data, the proposed protocol and the names of investigators and facilities to be used. Each phase of clinical research is described below.

Human safety trials (Phase I)

This phase is undertaken on healthy subjects to establish pharmacokinetic and pharmacodynamic profiles. To establish the pharmacokinetic profile, work is undertaken to determine drug levels in blood and urine in relation to dosage. To establish the pharmacodynamic profile, work is undertaken to measure the extent to which an administered drug exerts a specified action over time.

Early efficacy trials (Phase II)

These clinical trials are performed on patients who have the specific condition or disease that the test drug is intended to treat. The trials may be open or controlled. Open trials are performed only with the test drug. Controlled trials compare the test drug to either a placebo (inactive substance) or another known drug entity within the same therapeutic category. The data is recorded on a per patient basis in case report forms. Case reports contain the dosing schedule, clinical and laboratory measurements, adverse reactions and any other information the investigator may feel is relevant.

Expanded therapeutic trials (Phase III)

These trials are designed to expand knowledge of the safety and efficacy of the test drug. The comparative drug used as the known standard in this phase can be a competitive product that is already in general use. In addition to establishing safety and efficacy profiles, the data obtained may clarify interactions with other medication taken at the same time.

Post approval or general usage trials (Phase IV)

These trials are usually conducted beyond the point at which the new drug is released for sale to the general public. Clinical trials in this phase are often undertaken to identify unexpected adverse reactions that may occur on wide range use of the new drug. There may also be studies undertaken to investigate drug interaction characteristics or the effectiveness of a given drug on specific target groups.

Eligible clinical trials

When considering the issue of clinical trials undertaken in Canada to meet regulatory requirements, eligibility can only be determined on a case by case basis. One must determine whether the work complies with the definition of SR&ED specified in subsection 2900(1) of the Regulations. Information Circular IC86-4 explains this definition and outlines three eligibility criteria as follows: scientific or technological uncertainty, scientific or technological advancement, and scientific or technical content. Clinical trials must satisfy these criteria to comply with subsection 2900(1) of the Regulations.

Clinical trials as studies undertaken in Canada that would constitute SR&ED

Clinical trials as studies undertaken by the taxpayer in Canada to meet the Phase I, II and III requirements of a New Drug Submission (NDS) are eligible as SR&ED as long as the three eligibility criteria are satisfied. Studies must be supported by documentation to substantiate that data analysis and interpretation were undertaken by the taxpayer in Canada in an effort to achieve scientific or technological advancement, whereas data collection or testing alone is not sufficient. Examples of eligible cases are: clinical studies undertaken to address scientific uncertainties associated with bioequivalency and clinical studies undertaken to investigate the intended effect of an experimental drug in an indication.

Phase IV clinical trials, which satisfy the three criteria are eligible under subsection 2900(1) of the Regulations.

When drug developers wish to change formulations, dosage regimens, routes of chemical synthesis or claim new therapeutic indications for a drug, a change to a NDS may be needed. This change is achieved by way of a supplement to the NDS referred to as a Supplementary New Drug Submission (SNDS). In order to carry out clinical studies to support the SNDS, the drug developer must again obtain approval by filing a Preclinical New Drug Submission (PNDS). Such clinical trials meet subsection 2900(1) of the Regulations when the three eligibility criteria are satisfied.

Clinical trials in direct support of experimental development of a new or improved drug

Clinical trials undertaken in Canada that involve work described in paragraph 2900(1)(d) of the Regulations (such as data collection and testing) are eligible SR&ED, for the taxpayer undertaking the experimental development of a new or improved drug formulation in Canada.

Ineligible work associated with clinical trials

It does not follow that all work undertaken in Canada to meet regulatory requirements is eligible as SR&ED. For example, the provision of labels, product monographs, etc., is a regulatory requirement but their preparation is routine and not eligible as SR&ED.

Subsection 2900(1) of the Regulations states that SR&ED "... does not include work with respect to:

(e) Market research or sales promotion.
(f) Quality control or routine testing of materials, devices, products or processes.
(g) Research in the social sciences or the humanities.
(i) Commercial production.
(j) Style changes.
(k) Routine data collection."

The following work associated with clinical studies is not SR&ED under subsection 2900(1) of the Regulations and would not qualify for SR&ED investment tax credit purposes.

Market research or sales promotion

An example of market research or sales promotion is a trial usage project or "seeding trial" that is undertaken on an approved drug to obtain early feedback from the field.

Quality control or routine testing of materials, devices, products or processes

Examples of routine testing are as follows: phase IV clinical trials undertaken to monitor effects of long term treatment with a known drug; phase IV clinical trials undertaken to confirm results of previous studies that already established safety and efficacy in the intended use.

Revenue Canada – application policy

NUMBER: *SR&ED 96-09* DATE: September 4 1996

SUBJECT: *Eligibility of clinical trials to meet regulatory requirements*

ISSUE: Are all clinical trials undertaken in the pharmaceutical industry to meet the requirements of regulatory authorities eligible Scientific Research & Experimental Development (SR&ED) activities?

When considering the eligibility of clinical trials undertaken in Canada to meet regulatory requirements of the Health Protection Branch (HPB) of Health Canada, the work must comply with paragraph 2900(1) (a), (b), (c) or (d) of the Income Tax Regulations. The following situations may be encountered:

1. Clinical trials as studies undertaken in Canada that constitute eligible SR&ED.
2. Clinical trials in the form of testing or data collection, undertaken in Canada in direct support and commensurate with the needs of the taxpayer's eligible SR&ED in Canada, are eligible to that taxpayer.
3. Clinical trials that do not meet (A) or (B) are not eligible.
4. Other studies that are not eligible.
5. Clinical trials undertaken outside of Canada are subject to different tax treatment (under provisions of subsection 37(2) of the Income Tax Act).

Examples of (A):

Phase I, II and III* clinical trials that constitute studies to investigate the safety and efficacy of a drug in a new indication.

Examples of (B):

Phase I, II and III* clinical trials undertaken in direct support of the experimental development in Canada of new or improved drug formulations.

Examples of (C):

"Seeding trials" designed to obtain early market feedback (sales promotion).

Phase IV* trials that fall into the category of routine testing or routine monitoring such as those undertaken to identify additional unexpected adverse reactions from use of a drug.

Clinical trials in support of work done to alter palatability of a drug, or its colour (style change).

Examples of (D):

Post-marketing surveillance and post-approval clinical studies to confirm established safety and efficacy profiles.

Long-term collection of stability data and studies in pharmacoepidemiology (The Department's current administrative position is that studies in pharmacoepidemiology are not eligible).

Director Specialised Compliance Enhancement Division

Issued by: Tax Incentive Audit Section and Scientific Research Section.

Annex 4

R&D EXPENDITURE IN OECD HEALTH DATA 99

Notes to Health R&D tables supplied in Sources and Methods to OECD *Health Data 99*

General definitions

The following general definition is provided at the beginning of the specifications for the R&D variables:

Box A4.1. **General definitions of health-related R&D**

R&D is defined according to the following definition: "R&D programmes directed towards the protection and improvement of human health. It includes R&D on food hygiene and nutrition and also R&D on radiation used for medical purposes, biochemical engineering, medical information, rationalisation or treatment and pharmacology (including testing medicines and breeding of laboratory animals for scientific purposes) as well as research relating to epidemiology, prevention of industrial diseases and drug addiction". *Source: Frascati Manual*, OECD 1994d, p. 122.

The basic definition of ***biomedical research*** comprises: the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons; the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology. A full list of such activities includes clinical trials and laboratory investigations, the study of exposure to environmental agents and various behavioural hazards.

Health services research (related to the analysis of health delivery and financing processes), which is of great concern to policy analysts, is usually not included though in practical terms it may be difficult to distinguish whether some projects promote the life process or, solutions towards specific diseases, or alternatively, affect mainly specific target (client) groups of heath agencies.

Source: Sources and methods to total expenditure on health R&D.

Guidelines for individual series

Variables essentially derived from the OECD R&D database

Box A4.2. **BUDG: Central government budget on health research and development**

Data assembled by national authorities using statistics collected for budgets. This essentially involves identifying all the budget items involving R&D and measuring or estimating their R&D content. The series generally cover federal or central government only. Government appropriations budgeted by States or subordinated authorities for "creative work undertaken on a systematic basis in order to increase the stock of knowledge to devise new applications" with reference to healthcare in particular (*Frascati Manual*).

Source: Sources and methods to total expenditure on health R&D.

The series for this variable are GBAORD data for health as SEO from the OECD R&D database as described in Chapter 1. The source is given as *Main Science & Technology Indicators* (OECD, twice-yearly). It should actually be *Basic Science and Technology Statistics* (OECD, annual a). The exception is the United States for which the same figures as in the public expenditure on health R&D series below are given.

Box A4.3. **PHTO: Expenditure on pharmaceutical industry research and development**

Research and development activities undertaken by the corporate sector in order to develop new compounds to correct somatic or psychic dysfunction or to improve individuals' state of health, irrespective of the source of funding.

Source: Sources and methods to total expenditure on health R&D.

With one or two exceptions (Canada, Denmark, the United States) where industry sources are preferred, these series are those for total intramural R&D in the pharmaceutical industry drawn from the ANBERD and BERD databases as described Chapter 2. The source given is *Research and Development Expenditure in Industry* (several issues).

Variables essentially defined in OECD Health Accounts

Box A4.4. **DRPU: Public expenditure on health research and development**

Public (central or local administration or social organisation) financing of total expenditure on health research and development.

Source: Sources and methods to total expenditure on health R&D.

Box A4.5. **DRTO: Total expenditure on health research and development R&D**

The questionnaire and Sources and Methods do not give any definition of the coverage of this variable It is not Health GERD. Judging from the series quoted and national notes it should cover expenditure on R&D, which is not already included elsewhere in health expenditure. In consequence it should not include R&D in industrial firms (notably the pharmaceutical industry) as the expenditure is already included in production and sales or in hospitals. Given that education and training is another variable in the same chapter, it should presumably not include G.U.F.

Annex 5

GLOBAL BURDEN OF DISEASE GBD CLASSIFICATION

GROUP I			
Communicable, maternal, perinatal and nutritional conditions	A. Infectious and parasitic diseases	1. Tuberculosis	
		2. Sexually transmitted diseases	a. Syphilis b. Chlamydia c. Gonorrhea
		4. Diarrheoal diseases	
		5. Childhood cluster diseases	a. Pertussis b. Polio c. Diphteria d. Measles e. Tetanus
		6. Bacterial meningitis	
		7. Hepatitis B and C	
		8. Malaria	
		9. Tropical cluster diseases	a. Trypanoso miasis b. Chaga dis. c. Schistos. d. Leishmaniasis e. Lymphatic filariasis f. Onchoceriasis
		10. Leprosy	
		11. Dengue	
		12. Japanese encephalitis	
		13. Trachoma	
		14. Intestinal nematode infections	
	B. Respiratory infections	1. Lower respiratory infections	
		2. Upper respiratory infections	
		3. Otitis media	
	C. Maternal conditions	1. Maternal haemorrhage	
		2. Maternal sepsis	
		3. Hypertensive disorders of pregnancy	
		4. Obstructed labour	
		5. Abortion	
	D. Conditions arising during the perinatal period	1. Low birth weight	
		2. Birth asphyxia and trauma	
	E. Nutritional deficiencies	1. Protein-energy malnutrition	
		2. Iodine deficiency	
		3. Vitamin A deficiency	
		4. Iron-deficiency anaemia	

GROUP II		
Non communicable diseases	A. Malignant neoplasms	1. Mouth and oropharynx cancer
		2. Oesophagus cancer
		3. Stomach cancer
		4. Colon and rectum cancers
		5. Liver cancer
		6. Pancreas cancer
		7. Trachea, bronchus and lung cancers
		8. Melanoma and other skin cancers
		9. Breast cancer
		10. Cervix uteri cancer
		11. Prostate cancer
		12. Ovarian cancer
		13. Lymphoma and multiple myeloma
		14. Leukaemia
	B. Other neoplasms	
	C. Diabetes mellitus	
	D. Endocrine disorders	
	E. Neuro-pyschiatric conditions	1. Unipolar major depression
		2. Bipolar disorders
		3. Schizophrenia
		4. Epilepsy
		5. Alcohol use
		6. Dementia and other degenerative and hereditary disorders
		7. Parkinson disease
		8. Multiple sclerosis
		9. Drug use
		10. Post traumatic stress disorder
		11. Obsessive-compulsive disorders
		12. Panic disorder
	F. Sense organ diseases	1. Glaucoma
		2. Cataracts
	G. Cardiovascular diseases	1. Rheumatic heart disease
		2. Ischaemic heart disease
		3. Cerebrovascular disease
		4. Inflammatory heart disease
	H. Respiratory diseases	1. COPD
		2. Asthma

	I. Digestive diseases	1. Peptic ulcer
		2. Cirrhosis of the liver
		3. Appendicitis
	J. Genito-urinary diseases	1. Nephritis and nephrosis
		2. Benign prostatic hypertrophy
	K. Skin diseases	
	L. Musculo-skeletal diseases	1. Rheumatoid arthritis
		2. Osteoarthritis
	M. Congenital anomalies	1. Abdominal wall defects
		2. Anecephaly
		3. Anorectal atresia
		4. Cleft lip
		5. Cleft palate
		6. Oesophagal atresia
		7. Renal agenesis
		8. Down's syndrome
		9. Congenital heart anomalies
		10. Spina bifida
	N. Oral conditions	1. Dental caries
		2. Periodontal diseases
		3. Edentulism
Group III		
Injuries	A. Unintentional injuries	1. Road traffic accidents
		2. Poisonings
		3. Falls
		4. Drownings
		5. Other unintentional
	B. Intentional injuries	1. Self-inflicted injuries
		2. Violence
		3. War

Part II

NATIONAL EFFORTS TO MEASURE RESOURCES FOR HEALTH-RELATED R&D

This part of the report includes ten national contributions to the joint OECD/Statistics Canada exercise on measuring health R&D. Contributors were invited to follow a common plan for their national studies covering six main topics.

- Summary description of the national health science and innovation system (HSIS), its core and peripheral components and national specificities.
- Health-related R&D in national S&T budgets and in GBAORD.
- Measuring health-related R&D in the non-market/public sector.
- Measuring health-related R&D in the market/industry sector.
- Health-related GERD and R&D personnel: level and structure.
- Lessons for national and international survey practice and for the revision of the *Frascati Manual.*

The papers fall into three groups:

- Six countries, Austria, France, Israel, Norway, the United Kingdom and the United States prepared papers which more or less followed this plan. The data on health R&D were specially compiled for the papers, are generally not very detailed and are not official estimates of health R&D in the countries concerned.
- The papers for Australia, Canada and Denmark are based on studies undertaken mainly for national purposes and the data are official. Those for Australia and Denmark include a large number of detailed tables.
- Spain provided a short but revealing methodological note.

The papers are presented as Chapters 5 to 14, with the countries in alphabetical order.

Chapter 5

HEALTH RESEARCH AND EXPERIMENTAL DEVELOPMENT IN AUSTRALIA

by

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Introduction

This chapter presents statistics of health R&D carried out in Australia by businesses/organisations within the Business, General government, Higher education and Private non-profit sectors. The original version presented at the informal workshop covered the years 1992-93, 1994-95 and 1996-97. The main figures and comments for 1998-99 have been added from a recent feature article on health R&D in the report of the overall results of the national R&D survey (ABS, 2000).

Definition of health R&D

The Australian Standard Research Classification (ASRC) has been used as the basis for determining health R&D. The ASRC is the collective name given to a set of three related classifications, two of which, the Socio-economic Objective classification and the Field of Research classification, can be used to identify health R&D. The use of the Socio-economic Objective classification identifies all R&D with an objective/purpose of health, whereas the use of the Field of Research classification identifies all R&D undertaken using health disciplines.

Socio-economic objective classification (SEO)

This classification allows R&D to be categorised according to the purpose of the R&D as perceived by the data provider (researcher).

It consists of discrete economic, social, technological or scientific domains for identifying the purpose of the R&D. The categories take account of processes, products, health, education and other social and environmental aspects of particular interest.

The classification has a hierarchical structure comprised of five divisions, 20 subdivisions, 107 groups and 519 classes.

The following categories may be considered relevant when looking at health R&D:

- *Group 070400 Human pharmaceutical products* which covers R&D directed towards the manufacture of pharmaceutical products for use in the prevention, diagnosis and treatment of human diseases.

- *Class 071402 Medical instrumentation* which covers R&D directed towards the manufacture of medical instrumentation.

- *Subdivision 130000 Health* which covers R&D directed towards human health, including the understanding and treatment of clinical diseases and conditions and the provision of public health and associated support services.

- *Class 160604 Environmental health* which covers R&D directed towards understanding the surroundings of people and environmental issues pertaining to health.

- *Group 191000 Advancement of knowledge – Medical and health sciences* which covers pure basic research in the medical and health sciences.

R&D by the Business sector is not classified to the most detailed (class) level of the SEO classification. Therefore, for the purposes of this chapter, health R&D has been defined in terms of socio-economic objectives as R&D classified to:

- *Group 070400 Human pharmaceutical products.*

- *Subdivision 130000 Health.*

- Or *Group 191000 Advancement of knowledge – Medical and health sciences.*

Field of research classification (FOR)

This classification allows R&D activity to be categorised according to the field of research undertaken. In this respect, it is the nature of the R&D which is being examined rather than the activity of the performing unit or the purpose of the R&D.

It consists of a set of discrete categories which identify the research fields. These fields include recognised academic disciplines and related major sub-fields taught at universities or tertiary institutions, major fields of research investigated by national research institutions and organisations, and emerging areas of study.

The classification has a hierarchical structure comprised of two divisions, twelve subdivisions, 86 groups and 486 classes.

When looking at health R&D, the relevant category is Subdivision 100000 Medical and health sciences. Only R&D which is directly relevant to health and medicine is included in the subdivision. R&D in biological sciences without application to human health and disease is excluded.

Health (SEO) R&D

Health R&D defined in terms of socio-economic objectives

- Expenditure on health R&D was AUD 1 183 million in 1996-97, an increase of 16% on 1994-95 and 55% higher than in 1992-93. In 1998-99, it rose by 15% since 1996-97 to AUD 1 357 million.

- Health R&D expenditure has risen since 1992-93 both as a proportion of total R&D expenditure and as a proportion of Gross Domestic Product (GDP). In 1996-97, health R&D expenditure accounted for 13.5% of total R&D expenditure and 0.22% of GDP, rising to 15.4% of GERD and 0.23% of GDP in 1998-99.

- In 1998-99, expenditure on health R&D by the Higher education sector was AUD 651 million, accounting for 48% of total health R&D expenditure. The Business sector accounted for 22%, the General government sector 18% and the Private non-profit sector 12%.

- Health R&D was the major R&D activity of the Private non-profit sector, making up 88% of total R&D expenditure by that sector in 1998-99. In contrast, only 8% of total R&D expenditure by the Business sector in 1998-99 was classified as health R&D.

- Human resources devoted to health R&D in 1998-99 were 16 520 person-years, an increase of 8% on 1996-99 and 20% higher than in 1994-95.

- In 1998-99, the Higher education sector accounted for 9 471 person-years or 54% of the total human resources devoted to health R&D. The Business sector accounted for 11%, the General government sector 20% and the Private non-profit sector 11%.

- In 1996-97, current expenditure accounted for 92% of health R&D expenditure, with capital expenditure accounting for the remaining 8%. Labour costs accounted for 48% of the expenditure.

- The major source of funding for health R&D in 1996-97 was the Commonwealth government, which provided AUD 563 million (48%). Businesses provided AUD 304 million (26%) while AUD 131 million (11%) came from State governments.

- Of the AUD 257 million spent on health R&D by businesses in 1996-97, AUD 213 million (83%) was funded by businesses, with an additional AUD 20 million (8%) provided from overseas.

- The major source of funding of health R&D carried out by general government organisations in 1996-97 was the Government sector, with AUD 76 million (32%) from the Commonwealth government and AUD 94 million (39%) from State governments. Businesses provided AUD 28 million (12%).

- For higher education organisations, most of the funding for health R&D in 1996-97 was from the Commonwealth government (AUD 432 million or 80%). Businesses provided AUD 36 million (7%).

- The Commonwealth government was the source of funding for 30% (AUD 45 million) of health R&D expenditure by private non-profit organisations in 1996-97. State governments provided 10% (AUD 15 million), while businesses provided 18% (AUD 27 million).

- Applied research accounted for 39% of health R&D expenditure in 1996-97, with strategic basic research accounting for 26%, experimental development 18% and pure basic research 16%.

- Experimental development accounted for 54% of health R&D expenditure by the Business sector, with applied research accounting for a further 38%. Basic research was more predominant in the other sectors, accounting for 46% of expenditure by the General government sector, 52% of expenditure by the Higher education sector and 65% of expenditure by the Private non-profit sector.

- Researchers accounted for 66% of the person-years of effort devoted to health R&D in 1996-97.

- In 1998-99, 73% of health R&D expenditure and 79% of human resources devoted to health R&D were directed towards the socio-economic objective of Health, while 16% and 8% respectively were directed towards the socio-economic objective of Human pharmaceutical products, and 11% and 13%, respectively, towards the Advancement of knowledge in the medical and health sciences.

- The importance of the socio-economic objectives varied across sectors. In the Business sector, the major objective was Human pharmaceutical products, accounting for 53% of health R&D expenditure by the sector. The socio-economic objective of Health was the major objective for the other sectors, accounting for 96% of health R&D expenditure by the Private non-profit sector, 82% by the General government sector and 78% by the Higher education sector. The Advancement of knowledge in the medical and health sciences accounted for a further 19% of the Higher education sector health R&D expenditure.

Health (FOR) R&D

Health R&D defined in terms of fields of research

- Expenditure on health R&D was AUD 1 119 million in 1998–99, with the Higher education sector accounting for AUD 592 million or 53%. The Business sector accounted for 19%, the Government sector 17% and the Private non-profit sector 11%.

- Human resources devoted to health R&D in 1998-99 were 14 059 person-years, with the Higher education sector accounting for 8 482 person-years or 60%. The Business sector accounted for 9%, the General government sector 20% and the Private non-profit sector 10%.

- In 1996-97, current expenditure accounted for 93% of health R&D expenditure, with capital expenditure accounting for the remaining 7%. Labour costs accounted for 48% of the expenditure.

- The major source of funding for health R&D in 1996-97 was the Commonwealth government, which provided AUD 481 million (49%). Businesses provided AUD 236 million (24%), while AUD 117 million (12%) came from State governments.

- Applied research accounted for 40% of health R&D expenditure in 1996-97, with strategic basic research accounting for 26%, pure basic research 18% and experimental development 17%.

- Researchers accounted for 67% of the person-years of effort devoted to health R&D in 1996-97.

- In 1998-99, of the AUD 1 119 million spent on health R&D, AUD 466 million (42%) was in the Clinical services field. In 1996-97, the field of Public health research took AUD 122 million (12% of the total). This field was not separately available in 1998-99 when the second highest one was pharmacolosy with AUD 95 million (80%).

- The fields of Clinical sciences and Public health research were the major fields for expenditure by the General government and Higher education sectors, while for the Business sector they were Clinical sciences and Pharmacology, and for the Private non-profit sector, Clinical sciences and Immunology.

Table 5.1. **Health (SEO) R&D, by sector**

Sector	Expenditure AUD million				Human resources person-years			
	1992-93	1994-95	1996-97	1998-99	1992-93	1994-95	1996-97	1998-99
Business	151.9	226.5	257.2	304.4	1 146	1 588	1 740	1 851
General government	173.1	253.0	237.2	240.3	2 576	3 092	3 307	3 327
Higher education	352.3	404.0	537.1	650.8	6 871	7 651	8 258	9 471
Private non-profit	85.9	132.7	151.6	161.5	1 199	1 438	1 911	1 871
Total	763.1	1 016.2	1 183.2	1 357.1	11 792	13 769	15 214	16 520

Table 5.2. **Health (SEO) R&D expenditure, as a proportion of sector R&D expenditure and of GDP**
Percentages

Sector	Proportion of sector R&D expenditure				Proportion of GDP			
	1992-93	1994-95	1996-97	1998-99	1992-93	1994-95	1996-97	1998-99
Business	5.3	6.5	6.1	7.6	0.04	0.05	0.05	0.05
General government	9.5	12.8	11.3	11.6	0.04	0.05	0.04	0.04
Higher education	20.8	22.1	23.3	25.0	0.08	0.09	0.10	0.11
Private non-profit	84.3	85.2	88.4	87.3	0.02	0.03	0.03	0.03
Total	11.8	13.6	13.5	15.4	0.18	0.21	0.22	0.23

Table 5.3. **Health (SEO) R&D expenditure, by sector, by type of expenditure – 1996-97**
AUD million

Sector	Land and buildings	Other capital expenditure	Labour costs	Other current expenditure	Total
Business	4.3	14.9	101.4	136.7	257.2
General government	5.9	13.7	132.0	85.6	237.2
Higher education	9.5	25.3	253.1	249.3	537.1
Private non-profit	7.9	12.1	77.2	54.4	151.6
Total	27.6	66.0	563.7	526.0	1 183.2

Table 5.4. **Health (SEO) R&D expenditure, by sector, by source of funds – 1996-97**
AUD million

Sector	Commonwealth government	State government	Businesses	Other Australian	Overseas	Total
Business	9.7	0.1	213.2	14.6	19.7	257.2
General government	75.9	93.6	27.6	34.6	5.4	237.2
Higher education	432.2	22.3	35.9	36.7	10.1	537.1
Private non-profit	45.0	15.2	27.0	59.8	4.7	151.6
Total	562.8	131.2	303.7	145.5	39.9	1 183.2

Table 5.5. **Health (SEO) R&D expenditure, by sector, by type of activity – 1996-97**
AUD million

Sector	Pure basic research	Strategic basic research	Applied research	Experimental development	Total
Business	3.0	17.3	98.1	138.8	257.2
General government	33.7	75.6	107.4	20.5	237.2
Higher education	122.5	157.7	222.7	34.2	537.1
Private non-profit	35.7	62.7	38.2	15.0	151.6
Total	194.9	313.3	486.4	208.5	1 183.2

Table 5.6. **Human resources devoted to health (SEO) R&D, by sector, by type of employee – 1996-97**
Person years

Sector	Researchers	Technicians	Other supporting staff	Total
Business	995	500	245	1 740
General government	1 780	1 133	395	3 307
Higher education	6 284	n.a.[1]	1 972	8 256
Private non-profit	1 040	625	246	1 911
Total	10 099	2 258	2 858	15 214

n.a.: not available.

[1] Technicians for the Higher education sector not separately identified. They are included in other supporting staff.

Table 5.7a. **Health R&D expenditure, by sector, by socio-economic objective – 1996-97**
AUD million

Socio-economic objective	Business	General government	Higher education	Private non-profit	Total
070400 Human pharmaceutical products	146.9	33.2	16.5	1.4	197.9
130100 Clinical (organs, diseases and conditions)	83.8	126.4	258.8	102.6	571.5
130200 Public health	12.8	47.1	101.0	34.2	195.1
130300 Health and support services	7.5	25.7	53.7	1.1	88.0
130000 Health	104.0	199.2	413.5	137.9	854.6
19100 Advancement of knowledge – Medical and health sciences	6.4	4.8	107.2	12.4	130.7
Total	257.2	237.2	537.1	151.6	1 183.2

Table 5.7b. **Health R&D expenditure, by sector, by socio-economic objective – 1998-99**
AUD million

Socio-economic objective	Business	General government	Higher education	Private non-profit	Total
070400 Human pharmaceutical products	761.4	35.1	18.1	1.3	215.8
130100 Clinical (organs, diseases and conditions)	102.6	124.5	300.0	116.6	643.7
130200 Public health	14.2	47.6	146.4	37.4	245.5
130300 Health and support services	17.6	25.2	60.3	1.6	104.7
130000 Health	134.3	197.2	506.7	155.6	993.9
19100 Advancement of knowledge – Medical and health sciences	8.7	8.0	126.0	4.7	147.3
Total	304.4	240.3	650.8	161.5	1 357.1

Table 5.8. **Health R&D, by socio-economic objective**

Socio-economic objective	Expenditure				Human resources			
	1992-93	1994-95	1996-97	1998-99	1992-93	1994-95	1996-97	1998-99
	AUD million	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years	Person-years
070400 Human pharmaceutical products	125.1	182.4	197.9	215.8	971	1 315	1 392	1 403
130100 Clinical (organs, diseases and conditions)	413.0	488.2	571.5	643.7	7 125	6 820	7 838	8 313
130200 Public health	135.9	173.8	195.1	245.5	2 196	2 522	2 785	3 128
130300 Health and support services	45.6	59.4	88.0	104.7	738	1 045	1 336	1 529
130000 Health	594.4	721.4	854.6	993.9	10 058	10 388	11 959	12 970
19100 Advancement of knowledge – Medical and health sciences	43.6	112.4	130.7	147.3	764	2 066	1 862	2 147
Total	763.1	1 016.2	1 183.2	1 357.1	11 792	13 769	15 214	16 520

Table 5.9. **Health R&D, by businesses, by socio-economic objective**

Socio-economic objective	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
070400 Human pharmaceutical products	93.0	136.5	146.9	625	839	932
130100 Clinical (organs, diseases and conditions)	42.0	68.7	83.8	345	529	567
130200 Public health	6.9	9.5	12.8	69	79	97
130300 Health and support services	8.4	8.2	7.5	87	99	102
130000 Health	57.3	86.4	104.0	500	707	767
19100 Advancement of knowledge – Medical and health sciences	1.7	3.6	6.4	21	42	41
Total	151.9	228.5	257.2	1 146	1 588	1 740

Table 5.10. **Health R&D, by general government organisations, by socio-economic objective**

Socio-economic objective	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
070400 Human pharmaceutical products	25.8	37.4	33.2	209	330	287
130100 Clinical (organs, diseases and conditions)	81.0	129.4	126.4	1 506	1 733	1 966
130200 Public health	44.4	57.4	47.1	578	662	664
130300 Health and support services	14.0	20.7	25.7	177	275	336
130000 Health	139.4	207.5	199.2	2 261	2 670	2 967
19100 Advancement of knowledge – Medical and health sciences	7.9	8.1	4.8	106	92	53
Total	173.1	253.0	237.2	2 576	3 092	3 307

Table 5.11. **Health R&D, by higher education organisations, by socio-economic objective**

Socio-economic objective	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
070400 Human pharmaceutical products	6.3	6.5	16.5	136	134	151
130100 Clinical (organs, diseases and conditions)	214.8	199.3	258.8	4 230	3 546	3 957
130200 Public health	81.7	77.1	101.0	1 497	1 479	1 646
130300 Health and support services	22.5	29.4	53.7	460	655	883
130000 Health	319.0	305.7	413.5	6 187	5 680	6 487
19100 Advancement of knowledge – Medical and health sciences	27.0	91.8	107.2	548	1 837	1 618
Total	352.3	404.0	537.1	6 871	7 651	8 256

Table 5.12. **Health R&D, by private non-profit organisations, by socio-economic objective**

Socio-economic objective	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
070400 Human pharmaceutical products	[1]	2.0	1.4	[1]	12	22
130100 Clinical (organs, diseases and conditions)	75.3	90.8	102.6	1 044	1 012	1 347
130200 Public health	2.9	29.8	34.2	52	302	378
130300 Health and support services	0.6	1.2	1.1	14	18	14
130000 Health	78.8	121.8	137.9	1 109	1 331	1 739
19100 Advancement of knowledge – Medical and health sciences	7.1	8.9	12.4	89	95	150
Total	85.9	132.7	151.6	1 199	1 438	1 911

1. Nil or rounded to zero (including null cells).

Table 5.13. **Health (FOR) R&D, by sector**

Sector	Expenditure				Human resources			
	1992-93	1994-95	1996-97	1998-99	1992-93	1994-95	1996-97	1998-99
	AUD million	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years	Person-years
Business	n.a.	n.a.	178.7	211.2	n.a.	n.a.	1 169	1 293
General government	141.1	201.3	191.1	189.0	2 179	2 551	2 799	2 829
Higher education	314.3	375.9	491.4	592.4	6 196	7 103	7 575	8 482
Private non-profit	63.7	100.5	121.7	125.9	922	1 115	1 544	1 455
Total	n.a.	n.a.	982.9	1 118.5	n.a.	n.a.	13 087	1 4059

n.a.: not available.

Table 5.14. **Health (FOR) R&D expenditure, by sector, by type of expenditure – 1996-97**

Sector	Land and buildings	Other capital expenditure	Labour costs	Other current expenditure	Total
Business	2.3	10.4	69.0	97.1	178.7
General government	4.4	11.0	108.1	67.6	191.1
Higher education	6.0	22.8	232.4	230.1	491.4
Private non-profit	5.7	10.4	62.3	43.2	121.7
Total	18.4	54.6	471.8	438.0	982.9

Table 5.15. **Health (FOR) R&D expenditure, by sector, by source of funds – 1996-97**
AUD million

Sector	Commonwealth government	State government	Businesses	Other Australian	Overseas	Total
Business	3.6	0.1	155.8	5.8	13.5	178.7
General government	49.8	82.9	23.0	31.6	3.8	191.1
Higher education	391.2	21.8	33.7	35.5	9.2	491.4
Private non-profit	36.8	12.1	23.6	45.3	4.0	121.7
Total	481.4	116.9	236.1	118.2	30.5	982.9

Table 5.16. **Health (FOR) R&D expenditure, by sector, by type of activity – 1996-97**
AUD million

Sector	Pure basic research	Strategic basic research	Applied research	Experimental development	Total
Business	1.5	8.0	67.1	102.1	178.7
General government	30.2	56.2	89.1	15.5	191.1
Higher education	113.5	139.0	207.5	31.4	491.4
Private non-profit	27.3	50.3	30.4	13.6	121.7
Total	172.5	253.5	394.1	162.6	982.9

Table 5.17. **Human resources devoted to health (FOR) R&D, by sector, by type of employee – 1996-97**
Person years

Sector	Researchers	Technicians	Other supporting staff	Total
Business	667	333	169	1 169
General government	1 510	986	302	2 799
Higher education	5 758	[1]n.a.	1 817	7 575
Private non-profit	866	476	203	1 544
Total	8 801	1 796	2 490	13 087

n.a.: not available.

1. Technicians for the Higher education sector not separately identified. They are included in other supporting staff.

Table 5.18a. **Health R&D expenditure, by sector, by field of research – 1996-97**
AUD million

Field of research	Business	General government	Higher education	Private non-profit	Total
100100 Immunology	5.7	15.4	27.5	33.2	81.9
100200 Medical biochemistry and clinical chemistry	7.3	4.6	17.2	10.4	39.5
100300 Medical microbiology	3.0	16.9	15.3	7.5	42.7
100400 Pharmacology	57.9	6.8	42.1	1.8	108.5
100500 Physiology	np	3.4	25.6	3.4	n.p.
100800 Neurosciences	np	6.2	42.0	4.8	n.p.
100700 Clinical sciences	78.5	87.6	184.8	47.3	398.2
100800 Public health research	1.4	36.4	74.0	10.5	122.3
100900 Health services research	1.1	11.4	47.0	1.4	60.8
109900 Other medical and health sciences	11.6	2.5	18.1	1.5	31.6
100000 Medical and health sciences	178.7	191.1	491.4	121.7	982.9

n.p.: not available for publication but included in totals where applicable, unless otherwise indicated

Table 5.18b. **Health R&D expenditure, by sector, by field of research – 1998-99**
AUD million

Field of research	Business	General government	Higher education	Private non-profit	Total
100100 Immunology	11.0	15.9	32.1	24.9	83.9
100200 Medical biochemistry and clinical chemistry	8.0	2.8	16.4	4.3	31.6
100300 Medical microbiology	1.9	9.1	13.4	6.4	30.8
100400 Pharmacology	40.7	7.3	45.5	1.4	94.8
100500 Physiology	2.6	4.4	35.0	2.7	44.7
100600 Neurosciences	1.7	2.3	49.1	8.8	61.9
100700 Clinical sciences	84.1	100.6	216.8	64.9	466.4
100800 Public health research	2.1	27.1	100.9	n.p.	n.p.
100900 Health services research	3.5	15.7	60.9	n.p.	n.p.
109900 Other medical and health sciences	55.8	3.8	22.4	3.8	85.6
100000 Medical and health sciences	211.2	189.0	592.4	125.9	1118.5

n.p.: not available for publication but included in totals where applicable, unless otherwise indicated.

Table 5.19. **Health R&D, by general government organisations, by field of research**

Field of research	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
100100 Immunology	15.8	29.0	15.4	271	360	208
100200 Medical biochemistry and clinical chemistry	5.7	8.1	4.8	90	123	66
100300 Medical microbiology	10.2	15.5	16.9	208	236	194
100400 Pharmacology	6.6	8.5	6.8	102	89	98
100500 Physiology	6.3	4.0	3.4	53	43	39
100600 Neurosciences	4.8	3.2	8.2	80	31	107
100700 Clinical sciences	43.5	81.6	87.8	767	1 055	1 503
100800 Public health research	35.2	36.8	36.4	458	442	414
100900 Health services research	9.5	11.6	11.4	120	141	140
109900 Other medical and health sciences	3.0	3.1	2.5	28	31	30
100000 Medical and health sciences	141.1[1]	201.3	191.1	2 179[2]	2 551	2 799

[1] Includes AUD 0.6 million not reported against component fields.

[2] Includes two person years not reported against component fields.

Table 5.20. **Health R&D, by higher education organisations, by field of research**

Field of research	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
100100 Immunology	22.6	22.0	27.5	483	431	483
100200 Medical biochemistry and clinical chemistry	9.7	13.7	17.2	178	288	231
100300 Medical microbiology	11.1	11.8	15.3	237	263	263
100400 Pharmacology	21.1	25.3	42.1	461	443	524
100500 Physiology	20.8	22.8	25.6	347	388	398
100600 Neurosciences	31.9	37.0	42.0	529	567	591
100700 Clinical sciences	119.7	148.1	184.8	2 530	2 990	2 924
100800 Public health research	42.3	55.2	74.0	717	974	1 148
100900 Health services research	21.0	28.9	47.0	556	541	748
109900 Other medical and health sciences	13.9	13.4	16.1	159	218	270
100000 Medical and health sciences	314.3	375.9	491.4	6 196	7 103	7 575

Table 5.21. **Health R&D, by private non-profit organisations, by field of research**

Field of research	Expenditure			Human resources		
	1992-93	1994-95	1996-97	1992-93	1994-95	1996-97
	AUD million	AUD million	AUD million	Person-years	Person-years	Person-years
100100 Immunology	11.9	20.5	33.2	155	227	413
100200 Medical biochemistry and clinical chemistry	5.8	7.8	10.4	76	78	116
100300 Medical microbiology	6.1	11.9	7.5	80	138	123
100400 Pharmacology	1.7	1.2	1.8	27	19	24
100500 Physiology	5.1	4.2	3.4	80	49	35
100600 Neurosciences	3.7	3.9	4.8	51	39	53
100700 Clinical sciences	28.2	42.5	47.3	429	483	639
100800 Public health research	0.3	8.8	10.5	9	66	106
100900 Health services research	n.p.	0.9	1.4	n.p.	11	19
109900 Other medical and health sciences	n.p.	1.0	1.5	n.p.	6	18
100000 Medical and health sciences	63.7	100.5	121.7	922	1 115	1 544

n.p.: not available for publication but included in totals where applicable, unless otherwise indicated.

EXPLANATORY NOTES

Data sources

The statistics presented in this chapter were compiled from data collected from businesses/organisations in the ABS Surveys of Research and Experimental Development. The surveys were based on complete enumerations of businesses/organisations identified by the ABS as likely R&D performers.

The GDP figures used to derive R&D/GDP ratios were current at the time of manuscript finalisation [Australian National Accounts: National Income, Expenditure and Product, September Quarter 1999 (Cat. No. 5206.0)], and, at current prices, are as follows: AUD 427 281 million (1992-93); AUD 474 546 million (1994-95); and AUD 533 632 million (1996-97).

Definitions

R&D is defined in accordance with the OECD standard as comprising creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

For a more comprehensive interpretation of the definition of R&D activity, contact the ABS or refer to the OECD publication, *The Measurement of Scientific and Technological Activities* (*"Frascati Manual" 1993*), OECD, Paris, 1994.

Scope

The sector classification used in the compilation of these statistics is adapted from the guidelines specified by the OECD for use in the conduct of R&D surveys.

Four sectors are recognised:

- *Business* includes all businesses whose primary activity is the production of goods or services for sale to the general public at a price intended to cover at least the cost of production, and the private non-profit institutions mainly serving them.
- *General government* includes all Commonwealth, State and local government departments and authorities.
- *Higher education* is defined by the OECD as including all universities and other institutions of post-secondary education whatever their source of finance or legal status.
- *Private non-profit* includes private or semi-public incorporated organisations which are established with the intention of not making a profit.

Coverage

Exclusions from the survey are:

- Business sector for the R&D surveys excludes businesses mainly engaged in agriculture, forestry, and fishing [*i.e.* industries in Division A of the Australian and New Zealand Standard Industrial Classification (ANZSIC), 1993 (1292.0)], partly because of collection difficulties and partly because such businesses are believed to have very low R&D activity (agricultural R&D activity is generally carried out by specialised research institutes not included in ANZSIC Division A).

- General government sector excludes local government organisations because it is considered that their contribution to total R&D activity would be minimal. Public sector organisations mainly engaged in higher education (*e.g.* universities) are included in the Higher education sector while those mainly engaged in trading or financial activities are included in the Business sector.

- Higher education sector for the R&D surveys only includes universities. Technical and Further education colleges and other post-secondary institutions are excluded because it is considered that their contribution to total R&D activity would be minimal.

Socio-economic objective and field of research classifications

For more information on these classifications see the Australian Standard Research Classification, 1993 (Cat. No. 1297.0).

Comparability with previous statistics

The statistics for Higher education presented in this publication may not be strictly comparable due to changes in collection methodology. The 1994 and 1996 statistics were compiled from data collected by the ABS, whereas the 1992 statistics were compiled from data collected from universities by the Department of Employment, Education, Training and Youth Affairs (DEETYA). The data for 1996-67 are those from the original paper. Slightly revised figures are given in the ABS feature article from which the 1998-99 data have been derived.

Reliability of statistics

The statistics in this publication should be used with caution for the following reasons:

- Many data providers had to make estimates because their accounts do not separately record data on R&D activity.

- The OECD standard definition of R&D used in this survey differs in some respects from what respondents may regard as R&D activity, particularly since the definitions used within the Grants for Industry R&D scheme for the allocation of grants, and the 125% Tax Concession Scheme for tax deductibility for specific R&D activities undertaken within Australia, differ slightly from the R&D survey definition.

Unpublished statistics

Limited additional detailed R&D statistics are available at a charge from the ABS.

Related publications

Users may also wish to refer to the following publications:

- *Australian Standard Research Classification (ASRC), 1993* (Cat. No. 1297.0).
- *Research and Experimental Development, Business Enterprises, Australia, 1996-97* (Cat. No. 8104.0).
- *Research and Experimental Development, General Government and Private Non-profit Organisations, Australia, 1996-97* (Cat. No. 8109.0).
- *Research and Experimental Development, Higher Education Organisations, Australia, 1996* (Cat. No. 8111.0).
- *Research and Experimental Development, All Sector Summary, Australia, 1996-97* (Cat. No. 8112.0).
- *The Measurement of Scientific and Technological Activities ("Frascati Manual" 1993) OECD, Paris, 1994.*
- "Health R&D" in *Research and Experimental Development, All Sector Summary, Australia, 1998-99* (Cat. No. 8120.0).

Where figures have been rounded, discrepancies may occur between sums of the component items and totals.

Annex 1

SEO CATEGORIES FOR HEALTH

(*Note:* Data are available at the detailed (class) level for the General government, Higher education and Private non-profit sectors. For the Business sector, data are only available at the group level.)

Subdivision 070000	**Manufacturing**
Group 070400	**Human pharmaceutical products**
070401	Prevention – biologicals (*e.g.* vaccines)
070402	Diagnostics
070403	Treatments (*e.g.* chemicals, antibiotics)
070499	Other
Subdivision 130000	**Health**
Group 130100	**Clinical (organs, diseases and conditions)**
130101	Infectious diseases
130102	Immune system and allergy
130103	Blood disorders
130104	Neurological disorders
130105	Endocrine diseases (incl. diabetes)
130106	Cardiovascular diseases
130107	Inherited diseases
130108	Cancer and related disorders
130109	Surgical methods and procedures
130110	Respiratory diseases (incl. asthma)
130111	Hearing, vision and speech
130112	Oro-dental
130113	Digestive system
130114	Arthritis, bone and joint disorders
130115	Kidney diseases
130116	Reproductive medicine
130117	Skin and related conditions
130118	Other organs, diseases and conditions
130199	Clinical health not specific to particular organs, diseases and conditions
Group 130200	**Public health**
130201	Women's health
130202	Health related to ageing
130203	Child health
130204	Aboriginal health
130205	Substance abuse
130206	Occupational health (excl. economic development aspects)
130207	Environmental health
130208	Mental health
130209	Disease distribution and transmission
130210	Preventive medicine

130211	Dental health
130212	Nutrition
130213	Food safety
130214	Health status (e.*g.* indicators of "well-being")
130215	Social structure and health
130216	Behaviour and health
130299	Public health n.e.c.
Group 130300	**Health and support services**
130301	Health education and promotion
130302	Nursing
130303	Occupational, speech and physiotherapy
130304	Palliative care
130305	Diagnostic methods
130306	Evaluation of health outcomes
130307	Health policy evaluation
130308	Health policy economic outcomes
130399	Health and support services n.e.c.
Subdivision 190000	**Advancement of knowledge – natural sciences, technologies and engineering**
Group 191000	**Medical and health sciences**
191001	Medical and health sciences

Annex 2

FOR CATEGORIES FOR HEALTH

(*Note:* Data are available at the detailed (class) level for the General government, Higher education and Private non-profit sectors. For the Business sector, data are only available at the group level.)

Subdivision 100000	**Medical and health sciences**
Group 100100	**Immunology**
100101	Allergy
100102	Cellular immunology
100103	Humoral immunology and immunochemistry
100104	Immunogenetics
100105	Transplantation immunology
100106	Tumor immunology
100199	Immunology n.e.c.
Group 100200	**Medical biochemistry and clinical chemistry**
100201	Clinical chemistry
100202	Medical biochemistry: carbohydrates
100203	Medical biochemistry: lipids
100204	Medical biochemistry: nucleic acids
100205	Medical biochemistry: proteins and peptides
100299	Medical biochemistry and clinical chemistry n.e.c.
Group 100300	**Medical microbiology**
100301	Bacteriology
100302	Parasitology
100303	Virology
100399	Medical microbiology n.e.c.
Group 100400	**Pharmacology**
100401	Basic pharmacology
100402	Clinical pharmacology and therapeutics
100403	Toxicology
100499	Pharmacology n.e.c.
Group 100500	**Physiology**
100501	Human biophysics
100502	Cell physiology
100503	Systems physiology
100504	Comparative physiology
100599	Physiology n.e.c.
Group 100600	**Neurosciences**
100601	Autonomic nervous system
100602	Central nervous system
100603	Peripheral nervous system
100604	Cellular nervous system
100605	Sensory systems
100699	Neurosciences n.e.c.

Group 100700	**Clinical sciences**
100701	Anaesthesia
100702	Dermatology
100703	Cardiology
100704	Dentistry and oral surgery
100705	Endocrinology
100706	Foetal development and medicine
100707	Gastroenterology and hepatology
100708	Geriatrics
100709	Haematology
100710	Intensive care
100711	Infectious diseases
100712	Medical genetics
100713	Nephrology and urology
100714	Neurology and neuromuscular diseases
100715	Obstetrics and gynaecology
100716	Oncology and carcinogenesis
100717	Opthalmology and optometry
100718	Orthopaedics
100719	Otolaryngology
100720	Paediatrics and child health
100721	Pathology
100722	Psychiatry
100723	Psychology – clinical
100724	Radiology and organ imaging
100725	Radiotherapy and nuclear medicine
100726	Rehabilitation and therapy: occupational and physical
100727	Rehabilitation and therapy: hearing and speech
100728	Reproduction
100729	Respiratory diseases
100730	Rheumatology and arthritis
100731	Surgery
100732	Venereology
100799	Clinical sciences n.e.c.
Group 100800	**Public health research**
100801	Environmental and occupational health and safety
100802	Epidemiology and health information systems
100803	Mental health
100804	Nutrition
100805	Preventive medicine
100806	Primary health care
100899	Public health research n.e.c.
Group 100900	**Health services research**
100901	Human bioethics
100902	Health and community services research and evaluation
100903	Health care administration
100904	Health education and promotion
100905	Nursing
100999	Health services research n.e.c.
Group 109900	**Other medical and health sciences**
109901	Biomechanics
109902	Medical biotechnology
109999	Medical and health sciences n.e.c.

GLOSSARY

Applied research

Original work undertaken in order to acquire new knowledge with a specific application in view. It is undertaken either to determine possible uses for the findings of basic research or to determine new methods or ways of achieving some specific and predetermined objectives

Basic research

Experimental and theoretical work undertaken primarily to acquire new knowledge without a specific application in view. It consists of pure basic research and strategic basic research. Pure basic research is carried out without looking for long-term benefits other than the advancement of knowledge. Strategic basic research is directed into specified broad areas in the expectation of useful discoveries. It provides the broad base of knowledge for the solution of recognised practical problems.

Capital expenditure

Expenditure on the acquisition of fixed tangible assets such as land, buildings, vehicles, plant, machinery and equipment attributable to R&D activity.

Experimental development

Systematic work, using existing knowledge gained from research or practical experience, for the purpose of creating new or improved products/processes.

Field of research

Field in which the R&D activity was performed. The FOR classification is primarily structured around disciplines or activities. It describes what research is being performed.

Human resources devoted to R&D

The effort of researchers, technicians and other staff directly involved with R&D activity. Overhead staff (*e.g.* administrative and general service employees such as personnel officers, janitors, etc.) whose work indirectly supports R&D, are excluded.

Labour costs

Wages and salaries, overtime allowances, penalty rates, leave loadings, bonuses, commission payments, all paid leave, employer contributions to superannuation and pension schemes, payroll tax, fringe benefits tax, payments to contract staff on the payroll, severance, termination and redundancy payments and workers compensation insurance.

Other current expenditure

Expenditure on materials, fuels, rent, hiring, repairs, maintenance and data processing, etc., and the proportion of expenditure on general services and overheads which is attributable to R&D activity.

Other supporting staff

Skilled and unskilled craftspersons, secretarial and clerical staff directly associated with R&D activity.

R&D activity

Systematic investigation or experimentation involving innovation or technical risk, the outcome of which is new knowledge, with or without a specific practical application, or new or improved products, processes, materials, devices or services. R&D activity extends to modifications to existing products/processes. R&D activity ceases and pre-production begins when work is no longer experimental.

Researchers

Those involved with the conception and/or development of new knowledge, products, processes, methods and systems, and in the management of the projects concerned.

Socio-economic objective

The area of expected national benefit rather than the immediate objectives of the researcher. The SEO classification defines the main areas of Australian economic and social activity to which the results of research programs are applied. It describes the purpose of the research, *i.e.* why the research is being performed.

Technicians

Those performing technical tasks in support of R&D activity, normally under the direction and supervision of a researcher. These tasks include the preparation of experiments, the taking of records, the preparation of charts and graphs, and the coding of data.

Type of R&D activity

Comprises basic research, applied research and experimental development.

Chapter 6

MEASURING HEALTH R&D IN AUSTRIA

by

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This chapter was prepared specially to contribute Austrian experience to the discussion of the problems of measuring heath R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in Austria.

Summary description of the national health science and innovation system (HSIS), its core and peripheral components and national specificities

The faculties of medicine at the Austrian universities are the core of the national health science and innovation system. They include university departments ("Universitätsinstitute") dealing with the different disciplines of the medical sciences and the university clinics ("Universitätskliniken"). The university departments fall under the competence of the Federal government (until recently Ministry for Science and Transport, now Ministry for Education, Science and Culture), which means that the overwhelming proportion of their expenditures are financed by General University Funds (GUF), whereas major components of expenditures by university clinics are budgeted by the Ministry for Health.

The university clinics are Federal institutions situated on the premises of hospitals, which are themselves maintained by the *Länder* governments since hospitals generally fall under the competence of the *Länder* governments.

Health-related R&D activities are also performed at training hospitals outside the university system, which in the majority of cases are *Länder* institutions. Some of these R&D activities are concentrated in small specialised units (often with part-time personnel) which belong to the Ludwig-Boltzmann Association for Scientific Research and are situated at hospitals. In line with the *Frascati Manual* guidelines, this association it is classified to the government sector and is mainly financed by Federal and other public funds.

Further health-related R&D is performed in specialised units, particularly in the government sector (such as the Federal Institute for Health), and there are also a few units in the private non-profit sector and at the Austrian Academy of Sciences.

In the business enterprise sector (BES), health-related R&D is performed in specialised units, particularly in the so-called co-operative research institutes' sub-sector and, above all, in enterprises (companies) in the pharmaceutical and the medical appliances and instruments industries, which often co-operate closely with university R&D units.

In summary, health-related R&D outside the BES is concentrated in the university sector. Health-related R&D projects at universities and other R&D units are financed by public (mostly Federal) funds, particularly via the Scientific Research Promotion Fund (FWF), by the Ministry for Health and by the *Länder* governments.

In the BES, health-related R&D in companies is overwhelmingly financed from the own funds of the companies.

Health-related R&D in national S&T budgets and in GBAORD

General coverage in Federal and Länder budgets

The so-called *Federal R&D budget*, which is formally an Annex to the annual Federal Finance Act, covers all health-related R&D financed by the Federal government. The main components are GUF and funding earmarked for R&D within the university system (including funding of the university clinics), funding of the Scientific Research Promotion Fund (which also finances health-related R&D projects performed in various institutions), funding of other Federal institutions which perform or finance health-related R&D and earmarked funding for specific health-related R&D projects which may be budgeted by the Ministry for Health or by the Ministry for Science.

The Federal R&D budget is prepared and updated annually in close co-operation between Statistics Austria and the Ministry of Finance and the other Federal Ministries. The relevant *Frascati Manual* definitions and guidelines are followed as closely as possible.

As concerns *Länder budgets*, estimates of the R&D relevant budget appropriations of the nine *Länder* governments are prepared annually on the basis of and in analogy to the methodology applied to the Federal Budget. This is done in close co-operation between Statistics Austria and the respective *Länder* governments. The aggregate result of this exercise, *i.e.* the sum of the R&D relevant budget appropriations of the nine *Länder* governments, is included in the annual global estimate of Austrian GERD prepared by Statistics Austria. The detailed tables have not been published so far, and are only used for internal purposes of the *Länder* governments.

As the majority of Austrian *hospitals* (including the three major hospitals in Vienna, Graz and Innsbruck where all the university clinics are situated) are maintained and/or financed to a large extent by the *Länder* governments, their budgets are included in the respective *Länder* budgets. Since they have not been included in regular R&D surveys, their R&D funds are estimated according to conventions agreed between the *Länder* governments and Statistics Austria. In consequence, 4% of the total budgets of the three major hospitals where the university clinics are situated and 1% of the total budgets of the training hospitals maintained by the *Länder* governments are included in the estimates of the R&D relevant budget appropriations of the respective *Länder*. Other hospitals are not taken into account at all.

General coverage in GBAORD

The Austrian GBAORD data reported to the OECD Secretariat and to EUROSTAT refer *only to the Federal budget.* This is, according to the Austrian interpretation of the relevant SNA criteria, a consequence of the international recommendations (in NABS and – in a more flexible way – in the *Frascati Manual*) that primarily *central* government budget data should be included in GBAORD.

The R&D content of the different budget items and posts is identified primarily on the basis of the results of the full-scale performer-based R&D surveys. The coefficients used are checked and updated annually in co-operation between Statistics Austria and the respective ministries financing the R&D activities. The R&D content of new budget items or of budget items where no relevant survey results are available is identified and determined in close co-operation between Statistics Austria and the financing ministries and/or agencies.

The classification or distribution of GBAORD by *socio-economic objective (SEO)* is carried out on the basis of a national classification of SEO developed by Statistics Austria, comprising 21 categories and sub-categories and is, via concordances, fully compatible with the OECD and UNESCO classifications and, hence, with the chapters of NABS. No breakdown by two digits of the NABS chapter "health" (4.0 to 4.9) is available, so far.

As our main sources of information for identifying health-related R&D in GBAORD data are the very detailed results of our full-scale performer-based R&D surveys (where we classify R&D by detailed field of science and technology *and* by socio-economic objective), together with the annual analyses of the databases on the federally funded R&D projects ("Faktendokumentation") and on the R&D projects financed by the Scientific Research Promotion Fund (FWF), we are also in a position to sub-classify or distribute General University Funds (GUF) further by socio-economic objective.

This approach is adopted for all national uses of the SEO classification. For example, the GBAORD tables published in the annual Federal R&D report always give GBAORD data broken down by socio-economic objective where GUF is redistributed. Only when reporting to OECD and Eurostat do we follow the international guidelines and include total GUF in the SEO category "advancement of knowledge".

The difference in the figures is striking.

Table 6.1. **Effect of redistributing GUF in share of health in Federal GBAORD, 1999**

	Advancement of knowledge	Health
GBAORD figures as reported to OECD and EUROSTAT	79.7%	2.6%
GBAORD figures with GUF redistributed (for national purposes)	36.8%	22.3%

Source: Annex 1, Annex 2.

It is clear that the distribution of GUF leads to results which are far closer to reality and make more sense.

The two different approaches are illustrated in the tables on the Federal R&D budget broken down by ministry (and/or budget chapter) and socio-economic objective (OECD classification and NABS chapters) attached as Annex 1 and Annex 2. Version 1 is the version reported to OECD and Eurostat, which means that *total* GUF is included in the SEO category "advancement of knowledge", whereas in Version 2, GUF is redistributed by SEO.

We are also able to break down the SEO category "advancement of knowledge" including total GUF (*i.e.* as reported to the OECD and Eurostat) *by main field of science and technology*. This breakdown (for the Federal budget of 1999) is shown in Table 6.2.

Table 6.2. **Respective breakdown for the Federal budget, 1999**

Natural sciences	30.7%
Technological sciences (engineering)	11.3%
Medical sciences	26.6%
Agricultural sciences	3.3%
Social sciences	13.5%
Humanities	14.6%

Source: Federal R&D budget.

As mentioned above, data for the *Länder* are *not* included in Austrian GBAORD reported to OECD and Eurostat. For internal national purposes, we also classify the R&D relevant budget appropriations of the nine *Länder* governments by socio-economic objective. As the estimated R&D expenditures of the hospitals (see above) are an integral part of the R&D relevant budget appropriations of the *Länder*, it is not surprising that some 40% of the total *Länder* R&D budgets is devoted to the SEO category "health".

Table 6.3. **Effect on the share of health in Austrian GBAORD when *Länder* budgets are included, 1999**

	Total	Of which: SEO category "health"[1]	
		Million ATS	%
Federal R&D budget	16 930	3 783	22.3
R&D relevant budget appropriations of the *Länder*	2 722	1 104	40.6
Total	19 652	4 887	24.9

1. On the basis of GUF distributed between SEO.
Source: National budgets.

Measuring health-related R&D in the non-market/public sector

General method of identifying health-related R&D

The only sources are the performer-based surveys in the higher education, the government and the private non-profit sectors where all institutions or units whose main activity is medical sciences or whose main field of R&D is human health as an SEO (though in terms of scientific discipline such a unit may be classified to social sciences) are taken into account. In survey practice, this means, for example, that university departments belonging to a faculty of medicine will, as a rule, be regarded as performing health-related R&D and, hence, will be classified to the SEO category "health", although there will be cases where specific university departments of this faculty will be classified to "advancement of knowledge".

Coverage and R&D content

Apart from defining the borderline between "health" and "advancement of knowledge", there seems to be no problem in including units belonging to university medical faculties. Of course, health-related R&D will not be restricted to medical faculties and therefore relevant units in other faculties have to be included. There seems to be no problem in covering relevant health-related R&D units in other sectors of performance.

There are two major problems in surveying: university clinics and hospitals outside the university system.

Austrian *university clinics* are extremely complex and complicated organisational units. They are Federal and university institutions situated at hospitals maintained and to a large extent financed by *Länder* governments. The personnel are partly Federal (primarily the doctors), partly *Länder*, partly on a private contract basis, and their activities cover advanced or specialised medical care, teaching and R&D. Without giving full details of our survey methodology (which refers to expenditure and personnel), it should be emphasised that we carry out rather detailed *time-budget surveys* in which each RSE (*i.e.* each member of the scientific personnel) and each technician or equivalent staff has to fill in a one-page questionnaire (for the first time in our ongoing survey, an *electronic questionnaire*) in which he/she is also asked to distribute his/her working hours between the teaching, R&D and advanced medical care categories.

Table 6.4. **Percentage distribution of working hours of personnel at university clinics 1993**

	Teaching	R&D	Advanced medical care
Scientific personnel (RSE)	11.5	25.9	62.6
Technicians	8.8	24.6	66.6
Other supporting staff	15.2	20.9	63.9
Total	11.5	25.0	63.5

Source: National R&D survey.

After previous – not very successful – attempts to survey R&D activities in *hospitals outside the university system* by questionnaire, we decided, after consultations with the *Länder* governments and experts concerned, to include the R&D efforts of "normal" hospitals by way of a global estimation procedure of expenditures based upon the *Länder* budgets (see section on health-related R&D in national budgets and in GBAORD). No estimations of R&D personnel data for hospitals have been made, so far.

We are aware that this procedure is not fully satisfactory. In addition to these estimates of R&D expenditures, which we assume to cover a major part of R&D activities in hospitals outside the university system, we also include in our R&D surveys the small units belonging to the Ludwig-Boltzmann Association, which are situated at hospitals and perform rather specific medical research (often with part-time personnel). Therefore, to consolidate the obviously incomplete picture of Austrian hospitals' R&D efforts, it would be advisable to make a new attempt to include hospitals outside the university system in a proper questionnaire-based R&D survey.

Classifications

For all units engaged in health-related R&D in the non-market sector (with the exception of the hospitals outside the university system), all standard *Frascati Manual* breakdowns (source of funds, type of expenditure, type of activity, personnel by occupation and by level of qualification) are directly available. For hospitals, only the expenditure breakdowns are available.

The standard classification for Austrian R&D statistics is the detailed field of science and technology classification developed by Statistics Austria, which is fully compatible with the FOST classification of the *Frascati Manual* (Table 3.2) at the one-digit and two-digit levels. It includes as a reference, classification of more than 1 300 four-digit items, which are specifically adapted to the national situation. An excerpt from the Austrian FOST classification covering the one-digit "human medicine" class is attached as Annex 3.

All R&D performing units in the non-market sectors of performance (higher education, government, private non-profit) are classified to one of the 49 two-digit classes of the Austrian FOST classification and then aggregated to main fields of science and technology (one-digit class). In addition, all R&D performing units are also classified to one of the categories of the Austrian SEO classification.

Results of the 1993 survey show that the SEO category "health" includes not only units carrying out R&D in the medical sciences but also a few doing R&D in natural, technological, agricultural and social sciences.

Table 6.5. **R&D expenditure 1993**
Units with health as an SEO by main field of science

Natural sciences	4.4%
Technological sciences (engineering)	0.0%
Medical sciences, of which:	93.8%
University clinics	52.1%
Hospitals	19.1%
Agricultural sciences	0.4%
Social sciences	1.4%

Source: National survey.

Measuring health-related R&D in the market/industry sector

General method of identifying health-related R&D: coverage and R&D content.

The only sources are the performer-based surveys in the business enterprise sector. In the co-operative research institutes sub-sector, which amounts to 8% of total BERD, all institutions or units whose main activity is medical sciences or whose main field of R&D is human health are taken into account. In the so-called company R&D sub-sector, which amounts to 92% of total BERD, all enterprises (companies) whose principal economic activity is the production of pharmaceuticals (NACE Rev. 1, group 24.4) or of medical appliances and instruments (NACE Rev. 1, group 33.1) ought to be included. The R&D activities of services sector units undertaken for the industries listed above (NACE Rev. 1, groups 24.4 and 33.1) should also be taken into account as health-related R&D. The R&D efforts of all units specified above can be aggregated to find total health-related R&D in the BES.

The supplementary distribution of the R&D activity of companies (even of companies whose principal economic activity is neither the production of pharmaceuticals nor of medical equipment but who belong, for example, to the services sector) *by product field* can provide complementary data on health-related R&D. So far, we have no practical experiences on the relation between the breakdown by industry and by product field with respect to health-related R&D, but we are looking forward with great interest to the results of our ongoing R&D survey for reference year 1998.

No breakdown (distribution) of company R&D by socio-economic objective has been available, so far.

Classifications

Concerning the current BES survey for 1998, which covers manufacturing as well as services, all standard *Frascati* breakdowns (source of funds, type of expenditure, type of activity, personnel by occupation and by level of qualification) will be directly available for the units classified to NACE groups 24.4 and 33.1 and for the relevant R&D performing units in the institutes' sub-sector.

Health-related GERD and R&D personnel

As described above, the main sources of statistical data on health-related R&D in Austria are, on the one hand, the analyses of Federal R&D budgets and the corresponding analyses of the *Länder* budgets and, on the other hand, the national performer-based R&D surveys in all sectors of performance.

The budgetary analyses are conducted annually by Statistics Austria. The most recent year covered is 1999, the analysis of the current year (2000) is under preparation.

The last national R&D survey which covers, in principle, all sectors of performance, and for which results are available referred to 1993. The so-called "company R&D sub-sector" of the BES was surveyed by the Federal Economic Chamber, all other sectors and sub-sectors of performance were surveyed by Statistics Austria. In the "company R&D sub-sector", only manufacturing firms were surveyed. Hospitals outside the university system were not surveyed by questionnaire but an estimate of their R&D expenditures was included in the national total.

Austria: health-related R&D by sector of performance, 1993

Table 6.6. **Expenditure and personnel**
Million ATS

	Total GERD	Health-related GERD	Total FTE for R&D	FTE for health-related R&D
Higher education sector, of which:	11 081	3 606	7 135.7	1 889.9
University departments	7 717	1 015	5 778.5	903.3
University clinics	2 469	2 469	959.5	959.5
Other	895	122	397.8	27.1
Government sector,[1] of which:	2 815	1 043	2 107.3[2]	172.6[2]
Hospitals[3]	903	903	[3]	[3]
Private non-profit sector	83	30	100.4	33.6
Business enterprise sector, of which:	17 234	1 711	15 114.4	1 138.2
Company R&D[4]	15 756	1 582	13 758.7	1 052.4
Co-operative institutes' sub-sector and other	1 478	129	1 355.7	85.8
Total	**31 213**	**6 390**	**24 457.7**[1]	**3 234.3**[4]

1. Including units of the Ludwig-Boltzmann Association.
2. Personnel of hospitals outside the university system not included.
3. No data on R&D personnel of hospitals available.
4. Only data for pharmaceutical industry included.

Source: National R&D survey.

The summary table (Table 6.6) shows health-related GERD and full-time equivalents for health-related R&D broken down by sectors of performance derived from the results of the national R&D survey for 1993. Data are not included for companies whose principal economic activity is the production of medical appliances and instruments or for companies of the services sub-sector of the BES. Personnel data for hospitals outside the university system are excluded.

As concerns the breakdown by source of funds, it can be stated in very general terms that an overwhelming proportion of the R&D in the higher education, government and private non-profit sectors is financed by public (Federal and *Länder*) sources, whereas health-related R&D in the BES is generally funded by BES funds. This means, very roughly and in orders of magnitude that, in 1993, three-quarters of health-related GERD was financed by public sources and one-quarter by private BES sources.

In the ongoing national R&D survey on the reference year 1998, which covers all sectors of performance (including the services sector) and is conducted by Statistics Austria, it will be possible to separately identify data for companies in the medical appliances and instruments industry and to take into account data resulting from the distribution of the R&D activities of companies by product field.

Concluding remarks

As a preliminary reaction, it is suggested that the following items need further consideration and clarification with a view to improving the measurement of health-related R&D at the national and international levels:

1. GBAORD: Concept of central government (Federal/state/*Länder*/provincial).
2. GBAORD by SEO: Further distribution of GUF by SEO seems to be absolutely necessary.
3. SEO/FOST: Relation between SEO and FOST should be analysed and clarified (concerning GBOARD as well as concerning performer-based surveys).
4. Definition of "health-related R&D": Relation between FOST category "medical sciences" and SEO category "health".
5. Definition of "health-related R&D": Clinical trials – borderline of R&D.
6. Performer-based R&D surveys: Consistent classification/breakdown/distribution by socio-economic objective in all – or at least in the higher education, government and private non-profit – sectors? Identification of SEO category "health" in BES?
7. Performer-based R&D surveys: University clinics – major measurement problems.
8. Performer-based R&D surveys: Hospitals (particularly outside the university system) – major measurement problems of high priority
9. Performer-based R&D surveys: Classification by industry/product field in BES.
10. Performer-based R&D surveys: BES – NACE Rev. 1, group 33.1 (medical appliances and instruments) should be separately identified.

Annex 1

Federal R&D budget by SEO (OECD classification /NABS)

ATS thousand

As reported to OECD/Eurostat

	NABS 6 Agriculture	NABS 7 Industrial Development	NABS 5 Energy	NABS 2 4+2 5 Transport, Telecommunications	NABS 2 1 Urban & Rural Planning	NABS 3 Environmental Protection	NABS 4 Health	NABS 8 Social Development & Services	NABS 1 Earth and Atmosphere	NABS 10(GUF)+11 Advancement of Knowledge	NABS 9 Civil Space	NABS 13 Defence	NABS 12 NEC	NABS 99 Total
BKA	18 547	74	4 800	-	8 223	7 391	25 834	13 559	-	40 879	-	-	-	119 307
BMI	-	-	-	-	-	-	-	2 235	-	-	-	-	-	2 235
BMUKA	-	6 000	-	-	-	-	-	121 082	-	429 071	-	-	-	556 153
BMWV 14	16 378	270 215	31 421	235 566	15 421	126 087	273 032	128 879	280 471	10 436 992	3 275	-	20 034	11 837 771
BMAGS 15	-	-	-	-	-	-	32 846	25 708	-	-	-	-	-	58 554
BMAGS 17	-	-	-	-	-	-	21 882	-	-	2 150 869	-	-	-	2 172 751
BMUJF	-	-	-	-	-	224 968	-	3 570	-	-	-	-	-	228 538
BMAA	-	-	11 038	-	-	-	-	12 684	-	301	-	-	-	24 023
BMJ	-	-	-	-	-	-	-	1 000	-	-	-	-	-	1 000
BML	-	-	-	-	-	-	-	-	-	2 390	-	1 000	-	3 390
BMF	17 300	438 298	38 075	23 461	765	10 559	85 256	34 692	12 478	429 083	-	-	4 896	1 094 863
BMLF	482 138	26 431	-	-	-	8 286	-	17 250	4 476	-	-	-	-	538 581
BMWA	-	184 005	7 076	11 309	163	1 330	-	958	-	2 713	-	-	-	207 554
BMWV 65	-	45 505	5 897	33 944	-	-	-	-	-	1	-	-	-	85 347
SUMME	534 363	970 528	98 307	304 280	24 572	378 621	438 850	361 617	297 425	13 492 299	3 275	1 000	24 930	16 930 067

Annex 2

Federal R&D budget by SEO (OECD classification/NABS)
ATS thousand

National approach

	NABS 6	NABS 7	NABS 5	NABS 2 4+2 5	NABS 2 1	NABS 3	NABS 4	NABS 8	NABS 1	NABS 10(GUF)+11	NABS 9	NABS 13	NABS 12	NABS 99
	Agriculture	Industrial Development	Energy	Transport, Telecommunications	Urban & Rural Planning	Environmental Protection	Health	Social Development & Services	Earth and Atmosphere	Advancement of Knowledge	Civil Space	Defence	NEC	Total
BKA	18 547	74	4 800	-	8 223	7 391	25 834	13 559	-	40 879	-	-	-	119 307
BMI	-	-	-	-	-	-	-	2 235	-	-	-	-	-	2 235
BMUKA	-	6 000	-	-	-	-	-	121 082	-	429 071	-	-	-	556 153
BMWV 14	200 026	1 485 469	214 994	370 562	90 108	416 034	1 385 036	1 178 838	728 817	5 537 444	66 315	-	164 128	11 837 771
BMAGS 15	-	-	-	-	-	-	32 846	25 708	-	-	-	-	-	58 554
BMAGS 17	-	-	-	-	-	-	2 172 751	-	-	-	-	-	-	2 172 751
BMUJF	-	-	-	-	-	224 968	-	3 570	-	-	-	-	-	228 538
BMAA	-	-	11 038	-	-	-	-	12 684	-	301	-	-	-	24 023
BMJ	-	-	-	-	-	-	-	1 000	-	-	-	-	-	1 000
BML	-	-	-	-	-	-	-	-	-	2 390	-	1 000	-	3 390
BMF	23 454	479 571	44 229	28 319	3 227	20 276	166 551	67 763	26 405	224 342	648	-	10 078	1 094 863
BMLF	482 138	26 431	-	-	-	8 286	-	17 250	4 476	-	-	-	-	538 581
BMWA	-	184 005	7 076	11 309	163	1 330	-	958	-	2 713	-	-	-	207 554
BMWV 65	-	45 505	5 897	33 944	-	-	-	-	-	1	-	-	-	85 347
SUMME	724 165	2 227 055	288 034	444 134	101 721	678 285	3 783 018	1 444 647	759 698	6 237 141	66 963	1 000	174 206	16 930 067

Annex 3

Austrian classification of detailed fields of science and technology (ÖSTAT-SYSTEMATIK)[1,2]

Excerpt

3000	**Humanmedizin**	**Human medicine**
3100	**Anatomie, Pathologie**	**Anatomy, pathology**
3101	Allgemeine Anatomie	General anatomy
3102	Allgemeine Pathologie	General pathology
3103	Cytologie	Cytology
3104	Embryologie	Embryology
3105	Experimentelle Pathologie	Experimental pathology
3106	Funktionelle Pathologie	Functional pathology
3107	Histologie	Histology
3108	Krebsforschung	Cancer research
3109	Neuropathologie	Neuropathology
3110	Onkologie	Oncology
3111	Pathologische Anatomie	Pathological anatomy
3112	Psychopathologie	Psychopathology
3113	Röntgenanatomie	Radiographic anatomy
3114	Systematische Anatomie	Systematic anatomy
3115	Topographische Anatomie	Topographical anatomy
3116	Diagnostik in der Medizin	Medical diagnostics
3117	Funktionelle Anatomie	Functional anatomy
3200	**Medizinische chemie, medizinische physik, physiologie**	**Medical chemistry, medical physics, physiology**
3201	Allgemeine Physiologie	General physiology
3202	Balneologie	Balneology
3203	Biophysik	Biophysics
3204	Elektronenmikroskopie	Electron microscopy
3205	Elektro- und biomedizinische Technik	Electrical and biomedical techniques
3206	Humangenetik	Human genetics
3207	Krebsforschung	Cancer research
3208	Medizinische Biochemie	Medical biochemistry
3209	Medizinische Biologie	Medical biology
3210	Medizinische Chemie	Medical chemistry
3211	Medizinische Molekularbiologie	Medical molecular biology
3212	Medizinische Physik	Medical physics

3213	Medizinische Physiologie	Medical physiology
3214	Neurochemie	Neurochemistry
3215	Neurophysiologie	Neurophysiology
3216	Nuklearmedizin	Nuclear medicine
3217	Radiologie	Radiology
3218	Strahlenbiologie	Radiobiology
3219	Strahlenphysik	Radiophysics
3220	Strahlenschutz	Radiation protection
3221	Strahlentherapie	Radiotherapy
3222	Vergleichende Physiologie	Comparative physiology
3223	Zellbiologie	Cell biology / Cytology
3224	Cytogenetik	Cytogenetics
3225	Sonographie	Sonography
3226	Biomechanik	Biomechanics
3227	Magnet-Resonanz Tomographie	Magnetic resonance tomography
3228	Impfstoffentwicklung	Vaccine development
3300	**Pharmazie, Pharmakologie, Toxikologie**	**Pharmacy, pharmacology, toxicology**
3301	Homöopathie	Homeopathy
3302	Neuropharmakologie	Neuropharmacology
3303	Pharmakodynamik	Pharmacodynamics
3304	Pharmakognosie	Pharmacognosy
3305	Pharmakologie	Pharmacology
3306	Pharmazeutische Chemie	Pharmaceutical chemistry
3307	Pharmazie	Pharmaceutics
3308	Psychopharmakologie	Psychopharmacology
3309	Toxikologie	Toxicology
3310	Arzneiformenlehre	Drug morphology (-design)
3311	Phytochemie	Phytochemistry
3312	Pharmakokinetik	Pharmacokinetics
3313	Arzneimittel-, Arzneistoffanalyse	Drug analysis
3314	Impfstoffentwicklung	Vaccine development
3400	**Hygiene, Medizinische Mikrobiologie**	**Hygiene, medical microbiology**
3401	Allergieforschung	Allergy research
3402	Arbeitsmedizin	Occupational health
3403	Bakteriologie	Bacteriology
3404	Bakteriologisch-serologische Untersuchungen	Bacteriologic-serological investigation
3405	Berufskrankheiten	Occupational illnesses
3406	Blutgruppenserologie	Blood group serology
3407	Bluttransfusionskunde	Blood transfusion
3408	Epidemiologie	Epidemiology
3409	Hämatologie	Haematology
3410	Hygiene	Hygiene
3411	Immunologie	Immunology
3412	Krebsforschung	Cancer research
3413	Lebensmittelhygiene	Food hygiene
3414	Leukämieforschung	Leukaemia research
3415	Lufthygiene	Air hygiene

3416	Medizinische Mikrobiologie	Medical microbiology
3417	Parasitologie	Parasitology
3418	Präventivmedizin	Preventive medicine
3419	Rehabilitationsforschung	Rehabilitation research
3420	Serologie	Serology
3421	Seuchenforschung	Epidemic research
3422	Silikoseforschung	Silicosis research
3423	Sozialmedizin	Social medicine
3424	Spezifische Prophylaxe (Impfschutz)	Specific prophylaxis (protection by vaccination)
3425	Stressforschung	Stress research
3426	Tropenmedizin	Tropical medicine
3427	Umwelthygiene	Environmental hygiene
3428	Virologie	Virology
3429	Wasserhygiene	Water hygiene
3430	Neuroimmunologie	Neuroimmunology
3431	Diagnostik in der Medizin	Medical diagnostics
3432	Impfstoffentwicklung	Vaccine development
3500	**Klinische Medizin (ausgenommen Chirurgie and Psychiatrie)**	**Clinical medicine (excl. surgery and psychiatry)**
3501	Akupunktur	Acupuncture
3502	Allergieforschung	Allergy research
3503	Allgemeinmedizin	General medicine
3504	Andrologie	Andrology
3505	Augenheilkunde	Ophthalmology
3506	Balneologie	Balneology
3507	Chemotherapie	Chemotherapy
3508	Dermatologie	Dermatology
3509	Endokrinologie	Endocrinology
3510	Gastroenterologie	Gastro enterology
3511	Geburtshilfe	Obstetrics
3512	Geriatrie	Geriatrics
3513	Gynäkologie	Gynaecology
3514	Hals-, Nasen-, Ohrenkrankheiten	Ear, nose and throat illnesses
3515	Haut- und Geschlechtskrankheiten	Skin and venereal disease
3516	Hepatologie	Hepatology
3517	Hör-, Stimm- und Sprachstörungen	Hearing-, voice-, and speech defects
3518	Innere Medizin	Internal medicine
3519	Intensivmedizin	Intensive medicine
3520	Kardiologie	Cardiology
3521	Kieferchirurgie	Oral surgery
3522	Kinderheilkunde	Paediatrics
3523	Kreislauferkrankungen	Circulatory diseases
3524	Lungenheilkunde	Respiratory medicine
3525	Neonatologie	Neonatology
3526	Nephrologie	Nephrology

3527	Nuklearmedizin	Nuclear medicine
3528	Orthopädie	Orthopaedics
3529	Perinatologie	Perinatology
3530	Radiodiagnostik	Radiodiagnostics
3531	Radiologie	Radiology
3532	Rehabilitationsforschung	Rehabilitation research
3533	Rheumatologie und Herdgeschehen	Rheumatology
3534	Sozialmedizin	Public health
3535	Sportmedizin	Sport medicine
3536	Stoffwechselerkrankungen	Metabolic disease
3537	Strahlenschutz	Radiation protection
3538	Strahlentherapie	Radiation therapy
3539	Syphilidologie	Syphilidology
3540	Urologie	Urology
3541	Venerolgie	Venerology
3542	Zahn-, Mund- und Kieferheilkunde	Dentistry
3543	Angiologie	Angiology
3544	Klinische Chemie	Clinical chemistry
3545	Laboratoriumsdiagnostik	Laboratory diagnostics
3546	Physikalische Medizin	Physical medicine
3547	Computerunterstütze Diagnose und Therapie	Computer-aided diagnosis and therapy
3548	Diabetologie	Diabetology
3549	Implantologie	Implantology
3550	Sonographie	Sonography
3551	Pränatale Diagnostik	Prenatal diagnostics
3552	Diagnostik in der Medizin	Medical diagnostics
3553	Notfallmedizin	Emergency medicine
3554	Schmerztherapie	Pain therapy
3600	**Chirurgie and Anästhesiologie**	**Surgery and anaesthesiology**
3601	Akupunktur	Acupuncture
3602	Allgemeine Chirurgie	General surgery
3603	Anästhesiologie	Anaesthesiology
3604	Bluttransfusionskunde	Blood transfusion
3605	Experimentelle Chirurgie	Experimental surgery
3606	Intensivmedizin	Intensive medicine
3607	Kieferchirurgie	Oral surgery
3608	Kinderchirurgie	Paediatric surgery
3609	Mikrochirurgie	Microsurgery
3610	Neurochirurgie	Neurosurgery
3611	Nuklearmedizin	Nuclear medicine
3612	Orthopädie	Orthopaedics
3613	Plastische und Wiederherstellungschirurgie	Plastic and reconstruction surgery
3614	Transplantationschirurgie	Transplantation surgery
3615	Unfallchirurgie	Emergency surgery
3616	Gefäßchirurgie	Vascular surgery
3617	Herzchirurgie	Heart surgery

3618	Thorax- und hyperbare Chirurgie	Thorax and hyperbare surgery
3619	Gastro- intestinale Chirurgie	Gastro-intestinal surgery
3620	Implantologie	Implantology
3621	Laserchirurgie	Laser surgery
3622	Onkologische Chirurgie	Oncological surgery
3623	Schmerztherapie	Pain therapy
3624	Notfallmedizin	Emergency medicine
3700	**Psychiatrie and Neurologie**	**Psychiatry and neurology**
3701	Forensische Psychiatrie	Forensic psychiatry
3702	Hirnforschung	Brain research
3703	Hör-, Stimm- und Sprachstörungen	Hearing-, voice-, and speech defects
3704	Kinder- und Jugendpsychiatrie	Child and juvenile psychiatry
3705	Klinische Psychiatrie	Clinical psychiatry
3706	Medizinische Psychiatrie	Medical psychiatry
3707	Medizinische Psychotherapie	Medical psychotherapy
3708	Mikrochirurgie	Microsurgery
3709	Neurochirurgie	Neurosurgery
3710	Neurologie	Neurology
3711	Neuropathologie	Neuropathology
3712	Neuropharmakologie	Neuropharmacology
3713	Neurophysiologie	Neurophysiology
3714	Psychoanalyse	Psychoanalysis
3715	Psychopathologie	Psychopathology
3716	Psychopharmakologie	Psychopharmacology
3717	Psychosomatik	Psychosomatics
3718	Rehabilitationsforschung	Rehabilitation research
3719	Sozialpsychiatrie	Social psychiatry
3720	Suchtforschung	Addiction research
3721	Tiefenpsychologie	Depth psychology
3722	Verhaltenstherapie	Behavioural therapy
3723	Sonder- und Heilpädagogik	Orthopaedagogy
3724	Neuroimmunologie	Neuroimmunology
3725	Diagnostik in der Medizin	Medical diagnostics
3800	**Gerichtsmedizin**	**Forensic medicine**
3801	Forensische Psychiatrie	Forensic psychiatry
3802	Gerichtliche Humanmedizin	Forensic human medicine
3803	Gerichtliche Veterinärmedizin	Forensic veterinary medicine
3804	Gerichtliche Chemie	Forensic chemistry
3900	**Sonstige und Interdisziplinäre Humanmedizin**	**Other and interdisciplinary human medicine**
3901	Biostatistik	Biostatistics
3902	Elektronenmikroskopie	Electron microscopy
3903	Geschichte der Medizin	History of medicine
3904	Homöopathie	Homeopathy
3905	Humanmedizin Interdisziplinär	Interdisciplinary human medicine
3906	Medizinische Computerwissenschaften	Medical computer sciences

3907	Medizinische Dokumentation	Medical documentation
3908	Medizinische Kybernetik	Medical cybernetics
3909	Medizinische Statistik	Medical statistics
3910	Verkehrsmedizin	Traffic accidents medicine
3911	Ökonomie des Gesundheitswesens	Public health
3912	Computerunterstütze Diagnose and Therapie	Computer-aided diagnosis and therapy
3913	Gentechnik, -technologie	Gene technology
3914	Gerontologie	Gerontology
3915	Medizinsoziologie	Medical sociology
3916	Ergonomie	Ergonomy
3917	Ernährungswissenschaften	Nutritional sciences
3918	Fachdidaktik (Humanmedizin)	Technical didactics
3919	Krankenhausökonomie	Hospital economics
3920	Notfallmedizin	Emergency medicine
3921	Patientenrechte	Patients' rights
3922	Umweltmedizin	Environmental medicine

1. Provisional translation into English prepared by the Vienna University of Agricultural Sciences.
2. Some of the reference keywords listed, particularly those of an interdisciplinary nature, may also appear under another main or detailed FOST (one- or two-digit).

Chapter 7

ESTIMATES OF GROSS EXPENDITURES ON R&D IN THE HEALTH FIELD IN CANADA

by

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This chapter was prepared specially to contribute Canadian experience to the discussion of the problems of measuring heath R&D.

Estimating health-related R&D expenditures in Canada

Introduction

Statistics Canada has been producing gross domestic expenditures on research and development (GERD) in statistical series since the early 1960s. This series is constructed by adding together the intramural expenditures on R&D as reported by the performing sectors. Since 1991, the agency has also been producing, upon special request, estimates of the health portion of GERD for one or more of the three Canadian Granting Councils: the Natural Sciences and Engineering Research Council; the Canadian Institutes for Health Research; and the Social Sciences and Humanities Research Council. The year 1999 marks the first year in which Statistics Canada published an estimate of health R&D spending in Canada, covering the period from 1970 to 1998 (Statistics Canada, 1999a and 1999b). These are the most recent data on health GERD at point of writing this chapter. The material below is drawn largely from the working paper prepared for this public release (ST-99-04) and from the actual Service Bulletin (Vol. 23, No. 4) containing the health GERD estimates.

Identifying the actors in health-related research

As with GERD, the health statistical series are constructed by adding together the intramural expenditures on R&D as reported by the performing sectors. GERD includes R&D expenditures reported in the natural sciences and engineering (NSE), and also the social sciences and humanities (SSH). Health sciences, being part of the NSE, are not specifically identified in the surveys being conducted by the Division. It is, therefore, necessary to estimate R&D expenditures in the health field by incorporating any relevant information and data available. Accordingly, the following sections give the definition of health GERD in each of the sectors and also the method used in each to prepare our estimates.

Health R&D performing sectors

Federal government: R&D programmes directed towards the protection and improvement of human health are included in the health GERD figures. Such programmes include R&D on food hygiene and nutrition and also R&D on radiation used for medical purposes, biochemical engineering, medical information, rationalisation of treatment and pharmacology (including testing of medicines and breeding of laboratory animals for scientific purposes), and research relating to epidemiology, and prevention of industrial diseases and drug addiction. The source of data on federal government R&D expenditures in health is the federal survey of government departments and agencies (Federal Science Expenditures and Personnel) which has been conducted annually since the 1960s. Data are collected on responses to a question on health as a socio-economic objective for R&D spending.

Provincial governments: R&D health estimates are based on values from provincial science surveys which show intramural R&D expenditures in the health field. Data for the province of Québec were not included prior to 1988 due to lack of available information.

Business enterprise sector: The Division conducts the annual Survey of Research and Development in Canadian Industries and aggregates the estimates for the pharmaceutical and medicines industry (SIC 3741) to be used for estimating health-field R&D conducted by this sector.

Higher education sector: Health R&D estimates for this sector are taken from total estimates of R&D performed by this sector. Total estimates are calculated using data from two main sources: the annual financial reports of the Canadian Association of University Business Officers on total university expenditures; and the University and Colleges Annual Staff Survey, conducted by Statistics Canada and giving faculty counts by teaching discipline and the three major fields of science. Assumptions are made, depending upon university size and teaching field, about the proportion of faculty time spent on R&D. R&D values are then calculated by field of science (including health) for this sector as a whole. To this health estimate are added estimates for R&D taking place at hospitals not already reported by universities. The actual source of R&D funds for these hospitals is still lacking, as is evident from Table 7.1.

Table 7.1. **Gross domestic expenditures on R&D (GERD) in the health field – 1998**
CAD million

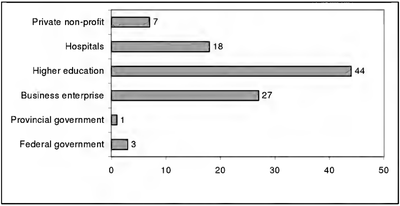
Funding sector	Federal government	Provincial governments	Business enterprise	Higher education[1]	Hospitals[2]	Private non-profit	Total
Federal government	74	-	4	266	..	23	367
Provincial governments	-	31	1	93	..	22	147
Business enterprise	-	-	462	124	..	19	605
Higher education[1]	-	-	-	273	..	-	273
Private non-profit	-	-	-	209	..	70	279
Foreign	-	-	140	23	..	12	175
Sub-total known funders	74	31	607	988	..	146	1 846
Unknown funders	..	..	..	..	410	..	410
Total	74	31	607	988	410	146	2 256

1. Includes hospitals covered by university reports.

2. Estimates for hospitals not covered by university reports and not previously included in higher education estimates.

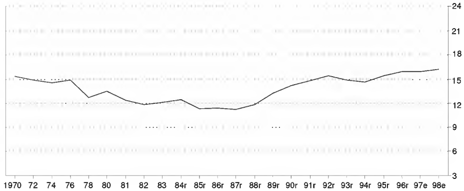
Private non-profit sector: An annual survey on R&D in this sector is conducted by Statistics Canada. Those expenditures identified as health-related by the respondents are used as a value for health R&D from this sector.

Figure 7.1. **Gross domestic expenditures on R&D (GERD) in the health field, by performer – 1998^{e}**
Percentages



e = estimated.

Figure 7.2. **Gross domestic expenditures on R&D (GERD) in the health field, compared to total GERD – 1970-98^{e}**



r = revised; e = estimated.

Table 7.2. **Gross domestic expenditures on R&D (GERD) in the health field, compared to total GERD –1970-98**[1]

Year	Hospitals not covered by university reports	Health GERD (including hospitals not covered by universities)	GERD	Health GERD/GERD
1970		164	1 069	15.3
1972		181	1 210	14.9
1974		217	1 797	14.5
1976		272	1 822	14.9
1978		294	2 319	12.7
1980		434	3 216	13.5
1981		494	4 020	12.3
1982		560	4 728	11.8
1983		607	5 023	12.1
1984^{r}	67	706	5 689	12.4
1985^{r}	81	781	6 904	11.3
1986^{r}	86	852	7 460	11.4
1987^{r}	85	883	7 865	11.2
1988^{r}	105	989	8 373	11.8
1989^{r}	136	1 170	8 887	13.2
1990^{r}	165	1 378	8 682	14.2
1991^{r}	190	1 495	10 123	14.8
1992^{r}	251	1 637	10 617	15.4
1993^{r}	211	1 701	11 394	14.9
1994^{r}	212	1 757	12 007	14.6
1995^{r}	272	1 914	12 466	15.4
1996^{r}	312	2 047	12 898	15.9
1997^{e}	358	2 137	13 473	15.9
1998^{e}	410	2 256	13 893	16.2

r = revised; e = estimated.

1. Values for hospitals not covered by university reports have not been added to GERD. This awaits further review of the data.

Improvement in the methodology for estimating health GERD

In the spring of 1999, Statistics Canada created a Working Group to review the methods used in the estimation of higher education R&D and health GERD and to make recommendations towards their improvement. Both areas impact directly on the quality of the national values published on health R&D because improvements in the former greatly affect the outcome of the other.

As was indicated above under the higher education sector, R&D estimates for the three fields of science, including health, are based upon certain assumptions about the amount of time faculty spend on R&D in addition to their other duties, such as teaching and community service. These assumptions are based on the size of the university and the nature of the discipline and teaching field. Generally, it is assumed that smaller universities will devote less time to R&D than larger ones, and that social sciences and humanities will conduct less R&D than the natural sciences and engineering. The Working Group recommended that these assumptions be put to the test since they have been in place for many years and, in any event, are not entirely founded upon Canadian experiences. The improvement plan produced as a result of the recommendations of the Working Group includes plans to conduct a sample survey or surveys of the university community to strengthen the basis upon which estimation methodologies and formulae will rest in the future. Clearly, the estimations of health R&D as a subset of this activity will benefit from this survey effort in the higher education sector.

Further, the Working Group recommended that Statistics Canada improve its coverage of hospitals and institutes so that a full accounting of health R&D be realised. Currently, the data sources for hospital R&D data include Statistics Canada's Annual Return of Health Care Facilities (from 1984-85 to 1994-95), and the Annual Hospital Survey conducted by the Canadian Institute for Health Information (from 1995-96 to the present). Statistics Canada's Centre for Education Statistics also provides a list of university-affiliated hospitals together with an indication as to whether the university has included, partially included, or excluded the research money of its affiliates in its report on university expenditures. The improvement plan calls for the provision of better information in this respect by the universities, thus enabling Statistics Canada to determine more precisely the expenditures affiliated hospitals and institutes are making in health R&D.

The Working Group also recommended, concerning the business enterprise sector, that health expenditures of relevant industries other than pharmaceuticals be considered for inclusion in the estimate. Accordingly, the improvement plan calls for an analysis of the Statistics Canada 1999-2000 Biotechnology Survey and also the annual Survey of R&D in Canadian Industries to locate R&D expenditures in the health field. Discussions will also begin with other areas inside and outside Statistics Canada concerning where relevant health-based research data may be found.

REFERENCES

STATISTICS CANADA (1999a), "Estimates of Gross Expenditures on Research and Development in the Health Field in Canada 1970 to 1998", *Bulletin of Science Statistics*, Vol. 23, No. 4, Ottawa.

STATISTICS CANADA (1999b), "Estimates of Gross Expenditures on Research and Development in the Health Field in Canada 1970 to 1998", Working Paper No. ST-99-04, Ottawa.

Chapter 8

R&D IN THE DANISH HEALTH SECTOR

by

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Introduction

This chapter presents the level and structure of research and development (R&D) in the Danish health sector in 1997. It is based on a study published in Danish as *Forskning og udviklingsarbejde ii sundhedssektoren: Forskningsstatistik 1997* (Analyseinstitut for Forskning, 1999).

The data were collected and analysed by the Danish Institute for Studies in Research and Research Policy on behalf of the Danish Ministry of Research and Technology. The questionnaire was prepared in co-operation with the Ministry of Health.

The study was prepared in line with OECD (1994), *The Measurement of Scientific and Technological Activities – Proposed Standard Practice for Surveys of Research and Experimental Development (Frascati Manual 1993).* The data are therefore comparable with other similar international studies.

The report focused on information about R&D in all Danish hospitals. In addition, it gave information about health faculties at universities, government research institutes and other types of public institutes that undertake health-related R&D. To put the data in context, some information was included about the R&D in the health-related industries in Denmark.

The data were collected by Jacob Jensen, assisted by Henrik Troelsen and Mads Bayer. The report was written by Henrik Troelsen in co-operation with Karen Siune.

This chapter varies slightly from the original report. It takes into consideration the effects of changes in the way R&D expenditures were accounted for in hospitals between 1995 and 1997 (Annex 3). It does not include the detailed information for all the individual hospitals or the lists of all the institutions surveyed which were annexed to the Danish version.

R&D in the total Danish health sector, 1997

Coverage of the public health sector

The figures in the report are derived from data collected for the report on R&D in the public sector in 1997, *Forskning og udviklingsarbejde I den offentlige sektor, Forskningsstatistik.* They cover R&D in health-related institutions as follows:

- University faculties and associated university hospitals.
- All other hospitals.
- Health-related government R&D institutes (the National Institute for Epidemiology, the Work Environment Institute, the State Serum Institute).
- A number of other public institutes that carry out health-related R&D.

Taken together, these institutions are referred to as public health-related institutions. (usually shortened to "public health sector").

The data on R&D in hospitals for 1997 are taken from a special survey of all Danish hospitals which covered a total of 964 departments, of which 326 (34%) reported R&D activity. This full survey is only carried out every ten years. The data for the earlier years included in this report (1991, 1993, 1995) include a number of estimates and are not strictly comparable with the new results for R&D expenditures.[1]

In addition to data from the regular R&D study of the public sector, information on market health-related R&D in 1997 is included, represented by data for the pharmaceutical and medical equipment industries from the industrial R&D survey.

Total R&D in the public health sector

In 1997, public health-related institutions spent DKK 1 891 million on R&D. This was down on 1995 by about DKK 195 million at current prices, giving apparent negative growth of -3% p.a. and -6% p.a. at fixed (1997) prices (Table 8.1). There is still a decline of about 2% p.a. over 1995-97 at fixed prices after adjustment for improvements in the survey of R&D in hospitals.

Table 8.1. **R&D in the public health sector**
DKK million

Year	1991	1993	1995	1997
Current prices	1 521	1 772	2 086	1 891
1997 (GDP) prices	1 673	1 898	2 171	1 891
Avg. annual growth (%), 1997 prices		6.5	7	-6.3

Source: Annex 2, Tables A1a and A1b.

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[1] The survey is described in Annex 1. Changes in methods are described in Annex 3.

Expenditures on health-related R&D were up 6.5% and 7% p.a. during the first half of the decade. The decline between 1995 and 1997 is surprising given the growth in the supply of funds from the Danish Medical Research Council over the same period as described in the Danish Ministry of Research and Technology and the Ministry of Health analysis of 1999: 6 *(Medicinsk Sundhedsforsknings vilkår og fremtid-med særligt henblik på sygehusområdet)*.

Human resources for R&D also moved in opposite direction to R&D expenditures between 1995 and 1997, rising from 3 588 R&D person-years in 1995 to 3 882 R&D person-years in 1997 (Table 8.2). The annual growth rate of 4% was slightly higher compared to the 1993-95 period, but less than the growth rate in 1991-93.

Table 8.2. **Person-years in the public health sector, 1991-97**

Year	1991	1993	1995	1997
Person-years	2 959	3 340	3 588	3 882
Avg. yearly growth (%)		6.2	3.6	4.0

Source: Annex 2, Table A1b.

Adding health-related R&D in the business sector

Expenditure on health-related R&D in the business sector, as represented by the pharmaceutical and medical equipment industries, came to DKK 2 955 million in 1997, up from DKK 2 353 million in 1995. However person-years worked on R&D declined from 3 654 in 1995 to 3 392 in 1997.

Taken together, the public and private sectors spent about DKK 5 billion on health-related R&D in 1997. Enterprises made the larger contribution to total expenditure whereas the public sector provided just over half of the 7 300 person years devoted to such R&D in Denmark.

International definitions

R&D comprises creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society. This stock of knowledge is used to devise new applications. The concept of R&D includes basic research, applied research, and experimental development.

- Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts without any particular application or use in view.

- Applied research is also original investigation undertaken in order to acquire new knowledge. However, it is directed primarily towards a specific aim or objective.

- Experimental development is systematic work that draws on existing knowledge gained from research and/or practical experience that is directed at producing new materials, products, and devices. It is also a factor in the installation of new processes, systems and services designed to substantially improve those already produced or installed.

R&D can be difficult to distinguish from certain other activities. It is common for all R&D activities to posses a certain element of novelty.

Health-related is a socio-economic objective (SEO) of R&D, aimed at the protection and improvement of human health. This category covers R&D programmes directed towards the protection and improvement of human health. It includes R&D on food hygiene and nutrition; radiation used for medical purposes, biochemical engineering; medical information; rationalisation of treatment and pharmacology (including the testing of medicines and the breeding of laboratory animals for scientific purposes): as well as research relating to epidemiology, prevention of industrial diseases and drug addiction.

Level and structure of R&D expenditure in the public health sector

Throughout this section all figures are at 1997 prices unless otherwise stated. In the tables in Annex 2, expenditures are shown at both fixed and current prices.

Coverage and funding categories

R&D activity is measured at, and reported by, the location at which it is performed. R&D expenditure can therefore be split into two categories:

- *Internally financed R&D expenditure*: the budgeted funds raised for R&D in the local individual institution.
- *Externally financed R&D expenditure*: the funds that are given or otherwise can be accounted for by the individual institute where R&D is performed. For example, a PhD student who works at a hospital but is paid by a university, should be included and counted at the hospital and not at the university. This category also includes funds from private foundations and the pharmaceutical industry.

Of the DKK 1 891 million spent in R&D in the public health sector in 1997, DKK 1 021 million were internally financed and DKK 871 million came from external sources. The decline in spending between 1995 and 1997 occurred in internal funding. R&D funding from external sources grew steadily over the 1990s (Table A3a in Annex 2).

R&D expenditure by type of institution

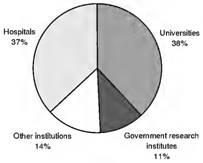
R&D expenditure in the public health sector can be broken down between universities, government research institutes, other health-related institutions and hospitals as shown in Figure 8.1.

These institutions fall into two pairs: the major performers, universities and hospitals, which together carry out 75% of the total; and the two minor ones, government and other institutes, which are responsible for the remaining 25%.

In 1997, *universities* were the largest sub-sector, spending DKK 750 million on R&D. Their expenditure fell slightly at fixed prices in 1991-93, but picked up thereafter. In 1997 *hospitals* spent DKK 700 million on R&D, slightly less than the universities. Trends are difficult to identify. If past estimation methods had been used, hospital R&D expenditure in 1997 would have been about level with 1995 at current prices and down by about 2% p.a. at fixed prices (Annex 3).

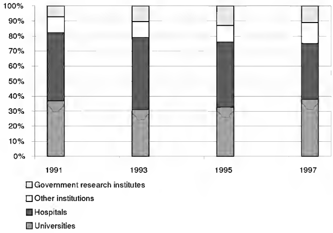
R&D spending by *other health-related institutions* rose steadily over the whole period and by 1997 they spent DKK 264 million or 14% of the total. There was a substantial fall in R&D expenditure in the *government institutions* between 1995 and 1997 (-14% p.a.), making them the smallest subgroup with 11% of the total.[2]

Figure 8.1. **R&D expenditure in the public health sector by type of institution – 1997**



Source: Annex 2, Table A1b.

Figure 8.2. **R&D expenditure in the public health sector by type of institution – 1991-97**



Source: Annex 2, Table A1b.

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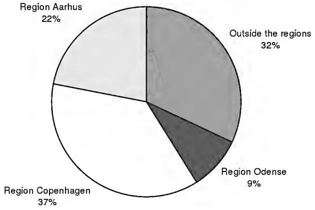
[2] After adjustment for changes in methodology the fall in spending at government institutes is twice that in hospitals.

R&D expenditure by region

R&D expenditures of hospitals and universities can be grouped into to regions (Annex 2, Table A2a). Figure 8.3 distinguishes three regions: the Copenhagen region, the Odense region and the Aarhus region.

Figure 8.3. **R&D expenditure in the public health sector, by region – 1997**



Source: Annex Table A2b.

The Copenhagen region is the largest of the three, accounting for 37% of total public health-related R&D expenditure in 1997. Next comes the Aarhus region, with 22% of the total. Last was the Odense region, which was responsible for 9% of the total. The remaining 32% of health-related R&D expenditure was not credited to any of the regions; this covers universities and hospitals in other regions (7%) plus health-related government research institutes and other health-related institutions. (25%)

Trends in the R&D expenditure shares by region[3] are shown in Figure 8.4. Copenhagen also dominated the health-related R&D in the past. Although its share of such R&D expenditure has been in continuous decline since 1991, it is still the largest spending region.

R&D expenditure in Aarhus rose continually over the decade, from DKK 332 million in 1991 to DKK 425 million in 1997. In Odense, funds for R&D have risen in the health faculties but have fallen in the hospitals connected to the university. Overall, the Odense region has experienced a slight decline in such R&D expenditure compared to 1995.

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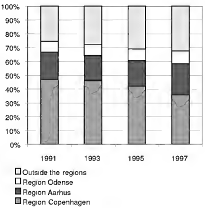
[3] It is not possible to adjust the R&D expenditures by region for changes in methodology for hospitals between 1995 and 1997.

Figure 8.4. **R&D expenditure in the public health sector, by region – 1991-97**

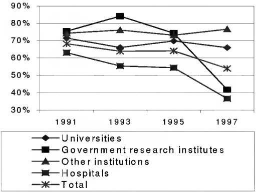


Source: Annex 2, Table A2b.

Internally and externally funded R&D expenditure by type of institution and by region

Figure 8.5 shows trends in the share of expenditure financed from internal sources in the four types of institutions. It reveals that, except in the small category of "other institutions", increasing use was being made of external funding. In the other three sub-sectors internally financed R&D actually fell at fixed prices between 1995-97 while external sources rose. The full survey of hospitals revealed that over 60% of their R&D was financed from external sources. Part of the rapid fall in the curve for hospitals on Figure 8.5 between 1995-97 is due to changed methods of calculating internal funding.

Figure 8.5. **Internally financed R&D expenditure by type of institution, as a percentage of the total R&D expenditure – 1991-97**



Source: Annex 2, Table A3b.

An analysis of trends in sources of funds in the different counties shows variations from one to another. In the counties of Aarhus and Funen, there was a significant growth in the share of external funds compared to that of internal sources for health-related R&D from 1991 to 1997. However, measured at 1997 prices, the externally financed funds did not rise during 1995-97 for the counties of Copenhagen, Funen, or North Jutland (as shown in Annex 2, Table A3a).

Health-related R&D expenditure by field of research

Throughout the 1990s, biomedicine was the largest field of research in health-related R&D in the public sector, as shown in Annex 2, Tables A4a and A4b. For example, in 1997, biomedicine had a share of DKK 755 million in the DKK 1 596 million for which we have information. The second largest field of research was clinical medical science, which appears to be declining according to our data. However, this decline is not valid, because Copenhagen University Hospital, which probably does a large amount of clinical medical research, did not supply the information needed to break down its R&D by field of research. The table also shows that the research in social medical science has risen significantly throughout the 1990s.

R&D expenditure in the public health sector by type of research activity

Table 8.3. **R&D expenditure by type of activity – 1991-97**

	1991	1993	1995	1997
Basic research	42%	41%	43%	38%
Applied research	40%	41%	38%	43%
Experimental development	18%	17%	19%	19%

Source: Biennial survey of R&D in the public sector.

Table 8.3 reveals a decline in the relative share of basic research and a comparable increase in that of applied research. Experimental development had the same share in 1997 as in 1995. This trend shows that research is becoming more focused to deal with specific areas and possibilities. The goals to be achieved through research are also becoming more focused. The trend in 1997 must be interpreted with caution because the University Hospital of Copenhagen did not report how their funds were distributed between the different kinds of research activity.

Human resources used in health-related R&D

Main categories

R&D personnel (head count) is defined as the number of people registered at the end of the survey year who have worked full- or part-time on R&D or its administration. (At least 5% of their paid time)

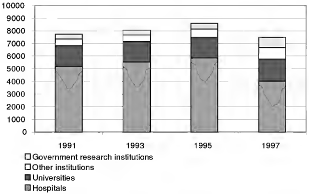
R&D person-years (unit) is defined as the equivalent of an employee who is working full-time on R&D. Thus two persons working half-time on R&D are equivalent to one person-year.

Trends can differ between the two series, as will be seen below.

Trends in human resources devoted to health R&D by type of institution

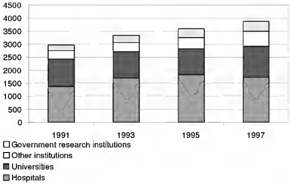
In head count terms, hospitals are the major employers of persons involved to some degree in health-related R&D. Numbers fell 1995-97 to a level below that of 1991.[4] Numbers employed on R&D fluctuated at universities but increased in 1997 at government institutes and other institutes. Overall, the public sector figures were lower in 1997 than in 1991 (Figure 8.6).

Figure 8.6. **Trends in R&D personnel (head count) in the public health sector, by type of institution – 1991-97**



Source: Annex 2, Table A5a.

Figure 8.7. **Trends in R&D person-years in the public health sector**



Source: Annex 2, Table A6b.

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[4] Personnel data for 1997 were collected from hospitals essentially on the same basis as for 1995.

However there was steady growth in total health-related R&D person-years with no sign of the decline in the public sector total in 1997 (Figure 8.7); this is because the increase in universities, government and other institutions outweighed the decline in person years worked on R&D in hospitals.

In the hospitals, there was a steady increase in the ratio of person-years to persons employed in R&D, which was particularly marked in 1997. This could mean that persons who carry out some research are spending more time on it but also that persons who do very little research are dropping out. This ratio varies for some survey years for the other sub-sectors.

Health-related R&D personnel distributed by region

Tables 8.4 and 8.5 show the trends in personnel and person-years involved in health-related R&D in the Copenhagen, Odense and Aarhus regions.

Table 8.4. **Trends in R&D personnel (head count), by region – 1991-97**

	1991	1993	1995	1997
Copenhagen	3771	4 042	4 126	3 020
Odense	711	887	1 002	653
Aarhus	1 376	1 324	1 428	1 395
Outside the regions	1 897	1 799	2 050	2 426
Total	7 755	8 052	8 606	7 494

Source: Annex 2, Tables A7a. and A7b.

Table 8.5. **Trends in R&D person-years, by region – 1991-97**

	1991	1993	1995	1997
Copenhagen	1 325	1 486	1 555	1 518
Odense	237	295	298	313
Aarhus	638	696	717	773
Outside the regions	759	864	1 018	1 278
Total	2 959	3 340	3 588	3 882

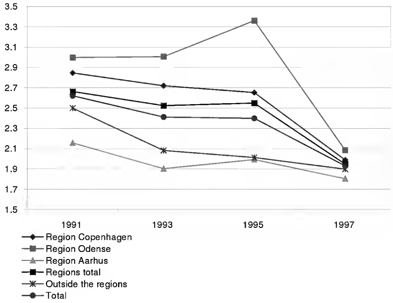
Source: Annex 2, Table A7b.

In 1997, the Copenhagen, Odense and Aarhus regions experienced a decline in the number of persons involved in health-related R&D though only Copenhagen also experienced a decline in person years worked on R&D. Despite the decline Copenhagen still contributed the largest share of health-related person-years (39%). Total personnel and person-years employed in health-related R&D grew outside these regions.

Trends in personnel compared to number of person-years by region

Figure 8.8 illustrates the general decline in the number of persons employed in R&D per person-year of health-related research in all the regions. This can be interpreted as showing that fewer people are needed to work one person-year which, in turn, can be taken to mean that persons who do carry out any research are spending a growing amount of their time on this activity. By 1997 there were more personnel involved in working a person-year in Odense (2.09) than in the other two specified regions (where the ratio was between 1.99 and 1.80).

Figure 8.8. **Trends in R&D head-count per person-year in the public health sector in three regions – 1991-97**



Source: Annex 2, Table A8.

Trends in expenditure (Annex 2, Table A2a) match those in person-years. In the Copenhagen region, R&D expenditure and number of person-years fell after 1995 whereas both grew in the Odense and Aarhus regions.

Public sector health-related R&D personnel and person-years by field of research

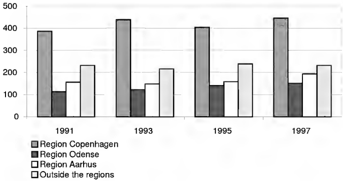
The distribution of personnel and number of person-years employed in health-related science by field of research is given in Annex 2, Tables A10a and A10b. They show that the concentration of personnel and person-years is most significant in the fields of biomedicine and clinical medical science.

The prime field for hospital research measured in person-years is biomedicine/biotechnology. The county of Aarhus leads this field, as shown in Annex 2, Table A11. Aarhus county is also dominant in the fields of neurology/psychiatry and in preventive health. The same table illustrates that the HS-region and the County of Copenhagen have made a significant commitment in the field of biomedicine/biotechnology. In 1997, the county of Funen made its highest contribution to preventive health. It also carried out a significant share of research in biomedicine/biotechnology. Most gerontological research was carried out in the capital city, but work is also conducted in the counties of Aarhus and Funen. It should be noted that the Copenhagen University Hospital did not supply information about field of research.

Trends in R&D by senior staff

Figures 8.9 and 8.10 illustrate the trends in the numbers of research professors and head doctors involved in R&D (head-count and person-years) in universities and hospitals in the specified regions.

Figure 8.9. **Trends in numbers of research professors and doctors, (head count) involved in R&D, by region – 1991-97**

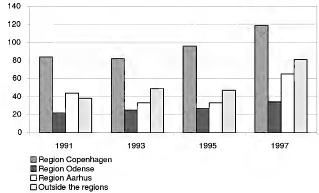


Source: Annex 2, Tables A12a and A12b.

The numbers of research professors and head doctors doing some R&D rose from 944 persons at end-1995 to 1 024 persons at end-1997. Of these, 44% were employed in the Copenhagen region. If the focus is changed from personnel to person-years, the numbers show significant growth over the decade . In 1997, such staff devoted 302 person-years to R&D. These were distributed as follows:

- 119 person-years in Copenhagen.
- 68 person-years in Aarhus.
- 34 person-years in Odense.
- 81 person years in hospitals and universities outside the three specified regions.

Figure 8.10. **Trends in the number of research professor and head doctors, person-years – 1991-97**



Source: Annex 2, Table A12b.

Further details on R&D in hospitals

Hospital R&D personnel and R&D person-years distributed by employment category and gender

Figures 8.11 and 8.12 illustrate the distribution of personnel and person-years in hospitals between different job categories and by gender.

The share of men and women carrying out some R&D work was broadly equal (Annex 2, Table A13a), and women accounted for a share of 56% of R&D person years (Annex 2, Table A13b). However, posts in higher authority, such as head doctors, head of department doctors and secondary doctors (reserve), are mainly occupied by men. Women predominate in nursing and technical-administrative staff posts. In PhD positions, there are equal numbers of men and women.

Some trends and types of expenditure in hospitals

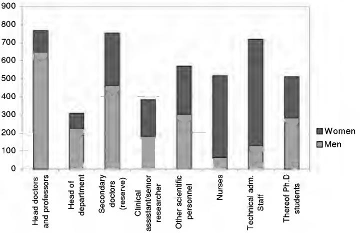
Table 8.6 illustrates the different finance and expenditure types that can be related to health R&D in Danish hospitals in 1997.

Table 8.6. **Source of funds and types of cost of R&D in hospitals – 1997**
DKK thousand

Types of finance	Types of costs				
	Salary	Equipment	Other	Total	Total in %
Internally financed	21 1236	9 209	35 586	256 031	37%
Pharmaceutical firms	35 414	2 836	6 639	44 889	6%
Funds	184 303	58 186	37 234	279 723	40%
Other financing	93 040	5 162	19 689	117 891	17%
Total	523 993	75 393	99 148	698 534	100%
Total in %	75%	11%	14%	100%	

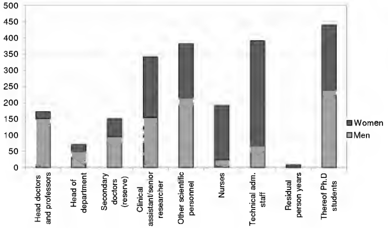
Source: Survey of R&D in hospitals, 1997.

Figure 8.11. **Hospitals: R&D personnel (head count), distributed by post and gender – 1997**



Source: Annex 2, Table A13a.

Figure 8.12. **Hospitals: R&D person-years, distributed by post and gender – 1997**



Source: Annex 2, Table A13b.

As noted above, over 60% of hospital R&D was funded from outside sources, 6% was financed by the pharmaceutical industry, and 57% was financed by various types of funds. The main part of the last category came from "other financing", which accounted for 40% of the R&D activity.

The table also shows that the salary costs absorb the largest part of expenditures on R&D. In 1997, salaries accounted for 75% of total R&D expenditure, equipment for 11% and "other expenditures" for the remaining 14%. Expenditure on equipment was mostly financed by funds (77% in 1997).

Health-related R&D in the business sector

This is represented by R&D in the pharmaceutical and medical equipment industries.

R&D expenditure

The pharmaceutical industry spent DKK 2.6 billion on R&D in 1997, more than the whole of the public health sector. The industry plays an important role in Danish industrial R&D contributing more than one-third of manufacturing BERD. The medical equipment industry spends about DKK 300 million on R&D, in the same range as government and other institutes in the public sector.

Health-related R&D expenditure in the business sector has grown significantly (Tables A5a and A5b). This is valid both for the pharmaceutical and medical equipment industry. Indeed, the pharmaceutical industry doubled its R&D between 1991 and 1997 (at current prices).

R&D personnel and R&D person-years

The pharmaceutical industry devoted 2 930 person-years to R&D in 1997, which involved 3 120 persons. It is the largest sub-sector for human resources for health-related R&D in Denmark but the difference is less striking than for expenditures. However R&D person-years in the medical equipment industry are similar to those for the two institutes categories (Annex 2, Table A9a).

The number of R&D personnel increased in the medical equipment industry between 1995 and 1997. This was outweighed by an 11% decline in R&D employment in the pharmaceutical industry, giving an overall decline in health-related R&D in the business enterprise sector. The trends in person-years in R&D were similar, with growth in medical equipment but a decline in the pharmaceutical industry. Overall health-related R&D person-years in the business enterprise sector were down by 7.7% compared with 1995. These trends in R&D personnel do not match those for R&D expenditure which continued to grow in both industries.

Key results of the study of public sector health-related R&D in Denmark

- In 1997, fewer people were involved in health-related R&D in the public sector in Denmark than ever before in the decade. On the other hand, there were more health-related R&D person-years tallied in 1997 than ever before.

- Expenditure on R&D in the public health sector has fallen since 1995. In 1997, DKK 1 891 million was spent, in comparison to the DKK 2 086 million spent in 1995. Calculated in 1997 prices, this equals an average decline of 6.3% per year, modified to 2% after adjustment for methodological changes.

- Health-related research at the universities has increased. Growth has been particularly substantial at the Royal Danish School of Pharmacy. The University of Copenhagen was the only university to experience a decline in R&D both in terms of expenditure and in person-years.

- A declining research effort was revealed in the hospitals in 1997. Employment on R&D fell by around 1 200 compared to 1995. However, measured in person-years, the decline is small. R&D expenditure also fell in the hospitals.

- Public health research is carried out mainly in environments connected to universities and county hospitals. Government research institutes carry out a declining share of Danish health research.

- Both the relative and absolute amounts of external funds used in health-related research increased.

- From 1991-97, there was an increase in the number of person-years devoted to R&D by head doctors and professors working in hospitals and universities. This matches the rise in the number of personnel employed at this level by the end of the period.

- In 1997, women carried out 56% of R&D person-years in Danish hospitals.

- The pharmaceutical industry financed 6% of total R&D in the hospitals in 1997, while funds and other institutions accounted for 40%.

- Overall, the business sector, represented by the pharmaceutical and medical equipment industries, carried out close to DKK 3 billion of R&D. This exceeds the R&D conducted in the public sector.

- The business contribution was lower in total personnel. Some 7 500 people were involved in R&D in the public health sector at the end of 1997 compared with 3,700 in the business sector.

- The shares were more even for R&D person-years. Of the 7 200 person-years devoted to health research in 1997, 3 882 were in the public sector and 3 392 in the business sector.

Annex 1

THE DATA COLLECTION PROCESS FOR HEALTH-RELATED R&D IN THE PUBLIC SECTOR IN 1997

In the public health sector, several different types of units were contacted. Among others, all the Danish hospitals, the health faculties at the universities, along with other public institutions that carry out health-related science, were contacted. When the assignment was made, the Ministry of Research and Technology informed the Danish Institute of Research and Research Policy (the Institute) that a total data collection for the research activity in all the hospitals should be made in 1997. Such a collection is carried out every ten years as a part of the total public R&D statistics collection exercise. The Ministry of Health had also intended to make a survey in 1997; however, since it would have otherwise been necessary to contact the same institutions twice with an almost identical questionnaire, the two surveys were combined into one.

The questionnaire

The questionnaire sent to the hospitals was designed in co-operation with the Ministry of Health. In designing the questionnaire, the Institute took into consideration its obligation to report the data collected to EUROSTAT and the OECD and thus to follow the instructions set out in the OECD's *Frascati Manual*. The *Frascati Manual* provides the foundation for the comparative statistics published each year by EUROSTAT and the OECD. It has served as the basic starting point for statistical comparisons in R&D in both the public and business sectors for a number of years.

According to the *Frascati Manual*, only paid R&D activity should be included in the figures. To fulfil this recommendation, this statistical report only includes personnel employed on R&D for more than 5% of their paid working hours. It must be noted that the Institute received a number of calls from hospitals where R&D was being carried out outside official working hours, and was thus "unpaid". An examination of these "unpaid" activities would provide us with a more complete picture of R&D activities than that disclosed in this statistical report.

Personnel and person-years for 1997 are registered in the same way as in the earlier surveys – although the earlier category "nurses and technical/administrative personnel" has been broken down into "nurses" and "technical/ administrative personnel". Furthermore, the person-years in the 1997 statistical report are broken down by gender, which was earlier only done for the personnel data.

Both expenditure and source of funds were accounted for, in principal, during the earlier studies. However, in 1997, they were combined into a matrix in the questionnaire with expenditure on the horizontal axis and finance on the vertical axis which may have had an impact on the data reported because the income and expenditure entries had to match. The impact on the responses, if any, should make the report more robust in terms of internal consistency.

R&D activity by field of research was estimated during the initial examinations. Unfortunately, information is missing from one significant institution, as mentioned below.

Compared to the earlier surveys, distribution by field of research has been specified in the health-related areas and a strategy there has been added. Otherwise the questionnaire has not changed significantly compared to the earlier surveys.

The survey population

The institutions that carry out health-related R&D in Denmark are of different types. Health-related research is an integral part of the work of the country's hospitals, universities and, especially university-related hospitals. This also applies to the Royal Danish School of Pharmacy and for the government research institutes. Furthermore, health-related R&D is also carried out in a few private hospitals. The reported data from these hospitals are incorporated in the statistical report of public health-related R&D in Denmark, 1997.

Unlike earlier surveys, data for 1997 were collected from all the hospital departments in the country. In conducting the survey, it became very clear that the population of such departments was not defined anywhere. The population from the 1995 survey was insufficient and, unfortunately, the official "Sygehusklassifikation" (hospital classification) did not match the actual situation in the hospitals. The Institute attempted to identify all the departments in the hope that the survey could be as useful as possible. All in all, the survey covers 964 departments.

The data collection procedure

In May 1998, a questionnaire was sent to the management of every hospital in the country. The material contained, along with the questionnaire, a letter describing the questions and how to answer them plus a return envelope. This procedure was chosen to make it as easy as possible for the hospital to answer the questionnaire. As it turned out, the mail delivery systems in the hospitals were often too effective and the questionnaire was often distributed to the departments before the management was able to decide whether their hospital should participate in the survey.

During the data collection process, many of the people responsible for filling out the questionnaire in the hospitals contacted the Institute to ask for assistance. Twice, new letters with questionnaires had to be sent out to departments that did not respond before the response deadline. By the end of the exercise, there were no known departments that had not "responded" to the questionnaire.

Validation and control of the incoming data

As the Institute received the questionnaires, they were controlled for internal coherence. A report was printed out for each hospital with the data reported by each department. These reports were then sent back to the hospitals for validation and control. In this way, the Institute allowed the management of the hospitals to check that their own data matched those supplied by the departments. It has been noted that the management in the hospitals distributed the material to the departments where the data had originally had been collected.

The Institute has endeavoured to ensure that the data collected provide a truthful picture of the reality. The hospitals have had their reported material returned for approval and have had the opportunity to change their own data as necessary. The reported and final data material can therefore be considered valid.

The largest institutional problem in collecting the data has been Copenhagen University Hospital. The hospital collected their own data for 1998 using their own questionnaire. It has not been possible for the Institute to obtain data from Copenhagen University Hospital for 1997, so 1998 information is used in this statistical report. This method was chosen instead of having Copenhagen University Hospital featuring as "unknown" for 1997. Unfortunately, the material received did not cover all the questions: field of research and kind of research activity statistics were not included (Annex 2, Tables A4a, A4b, A10a, A10b and A11).

The University of Aarhus reported a case of double counting in its return in relation to the clinical sector. It has been possible to precisely calculate the size of this double counting so that the tables now contain the correct data. The same problem appears to have occurred in 1995, and the data for this year have also been corrected.

Conclusions on the survey of R&D in the public health sector Denmark, 1997

The response rate for the exercise is almost 100% because the Institute received either a direct or indirect response from all the departments contacted. Because of this and the data validation process, it can be concluded that the survey gives a satisfactory picture of health-related R&D activity in the public sector Denmark in 1997.

In several instances, the numbers for 1997 show a turnaround compared to the trends described in earlier statistical reports, the latest of which was the 1995 report. Changes in the environment are seen as the largest explanatory factor for these differences. The following may have also had an influence:

- The data reported in the questionnaire are, in several instances, based on estimates. Both person-years spent in R&D and the distribution by kind of research activity are estimates. The data concerning the different fields of research activity are also estimates.

- The data showing personnel employed in R&D at the end of 1997 are more consistent, while numbers of person-years are again based on estimates.

- R&D finance and R&D expenditure have been calculated on the basis of estimated person-years used in the different departments. This can give rise to problems concerning external funding of employees who are paid by an institution where they do not physically work.

- In the earlier years, the questions on R&D expenditure included the goods and services tax. As prescribed by the *Frascati Manual*, the Institute did not ask about expenditures including the goods and services tax in 1997. One must therefore use caution in comparing the numbers.

- Some institutions may have changed their accounting methods in the interim period.

Annex 2

TABLES

General remarks

- Research on health topics in other units will not be included in this report.
- All figures in the tables are in DKK thousand.
- One person-year is the equivalent of a person working full-time on research and development.

Explanations

-	Means that the value is zero.
0	Means less than ½ of the concerned unit.
..	Means that the number is not available and is therefore not included in the total.
+	Means that the number is included in another cell.

Numbered notes to tables

1. Universities cover higher learning institutes, where there are faculties that can be defined as being health-related. In 1991, the Schools of Odontology were added to both the University of Copenhagen and Aarhus, where they have been included since.
2. In a smaller amount, some of the numbers from single institutes may have been estimated.
3. The government research institutions are: Dansk Institut for Klinisk Epidemilogi, Arbejdsmiljøinstituttet and the Statens Seruminstitut.
4. The category "other institutions" includes smaller health-related institutes outside the group of universities, hospitals and government research institutions.
5. The hospitals include all the hospitals in Denmark. The category entitled H:S covers a group of hospitals. The county of Frederiksberg and Copenhagen is included under H:S.
6. H:S includes the following hospitals: Bispebjerg, Frederiksberg, Sct. Hans, Amager, Hvidovre, Kommunehospitalet and Copenhagen University Hospital.

7. In the numbers mentioned the share of H:S has been deducted.

8. The estimates for the smaller hospitals concern the years 1991, 1993 and 1995. The estimate was made for use in the earlier statistical research reports because there had not been a total count. Naturally, there is no estimate for 1997 because in this year there was a total count.

9. By health faculty, we mean the health faculties in the universities

10. The numbers for Copenhagen University Hospital are for the year 1998.

11. Børne- og Ungdomspsykiatrisk Hospital was only included in 1997, hence there are no earlier data for this hospital.

12. The category "outside the regions" includes both hospitals and other institutions.

13. The total R&D expenditure by field of research. In the material, the data from Copenhagen University Hospital is missing because no information about the field of research was received.

14. Some institutions did not provide information on type of research activity, this includes Copenhagen University Hospital.

Table A1a. **Trends in R&D expenditure in health-related public institutions**
DKK thousand at 1997 prices

Institution	1991	1993	1995	1997
Universities(1)	618 968	590 857	711 788	720 259
The University of Copenhagen(2)	310 858	296 313	335 685	280 705
The University of Aarhus(2)	195 822	181 081	216 044	246 229
The University of Odense(2)	68 060	69 312	109 560	122 553
The Royal Danish School of Pharmacy	44 229	44 151	50 499	70 772
Government research institutions	120 960	195 718	279 817	207 703
Other institutions	175 353	200 380	239 489	264 192
Hospitals	757 923	910 739	940 138	698 534
H:S(6)	367 331	460 305	436 281	322 276
County of Copenhagen(7)	118 261	127 346	149 273	81 144
County of Frederiksborg(7)	+	+	+	6 740
County of Roskilde(7)	+	+	+	3 912
County of Storstroem	..	..	..	2 790
County of Bornholm	..	..	..	0
County of Westzealand	..	..	..	3 477
County of Funen	60 652	81 676	85 754	55 987
County of Ribe	..	..	..	1 506
County of South Jutland	..	..	..	1 303
County of Vejle	..	..	..	9 262
County of Aarhus	142 134	174 357	197 089	186 652
County of Viborg	..	..	..	3 738
County of Ringkoebing	..	..	..	5 775
County of North Jutland	23 264	18 013	21 073	13 972
Estimate for smaller hospitals	46 281	49 042	50 668	..
Total	**1 673 204**	**1 897 694**	**2 171 232**	**1 890 688**

Table A1b. **Trends in R&D expenditure in health-related public institutions**
DKK thousand at current prices

Institution	1991	1993	1995	1997
Universities[1]	562 766	551 979	683 814	720 259
The University of Copenhagen[2]	282 632	276 816	322 493	280 705
The University of Aarhus[2]	178 041	169 166	207 553	246 229
The University of Odense[2]	61 880	64 751	105 254	122 553
The Royal Danish School of Pharmacy	40 213	41 246	48 514	70 772
Government research institutions	109 977	182 840	268 820	207 703
Other institutions	159 430	187 194	230 077	264 192
Hospitals	689 104	850 813	903 191	698 534
H:S[6]	333 977	430 017	419 135	322 276
County of Copenhagen[7]	107 523	118 967	143 407	81 144
County of Frederiksborg[7]	+	+	+	6 740
County of Roskilde[7]	+	+	+	3 912
County of Storstroem	..	..	..	2 790
County of Bornholm	..	..	..	0
County of Westzealand	..	..	..	3 477
County of Funen	55 145	76 302	82 384	55 987
County of Ribe	..	..	..	1 506
County of South Jutland	..	..	..	1 303
County of Vejle	..	..	..	9 262
County of Aarhus	129 228	162 884	189 343	186 652
County of Viborg	..	..	..	3 738
County of Ringkoebing	..	..	..	5 775
County of North Jutland	21 152	16 828	20 245	13 972
Estimate of smaller hospitals	42 079	45 815	48 677	..
Total	**1 521 277**	**1 772 826**	**2 085 902**	**1 890 688**

Table A2a. **Trends in R&D expenditure in health-related public institutions in the three regions**
DKK thousand at 1997 prices

Institution	1991	1993	1995	1997
Region Copenhagen	784 289	874 124	912 442	676 674
Health faculty(9)	310 858	296 313	335 685	280 705
Copenhagen University Hospital(10)	273 176	327 565	295 771	232 561
Bispebjerg Hospital	20 154	28 724	29 933	25 219
Frederiksberg Hospital	5 731	8 281	8 456	6 345
Amtssygehuset, Herlev	57 797	68 641	88 245	47 596
Hvidovre Hospital	42 607	61 556	64 019	49 200
Amtsygehuset i Gentofte	41 681	31 548	26 528	7 541
Amtssygehuset i Glostrup	18 784	27 158	34 501	26 007
Københavns kommunehospital	13 502	24 338	29 304	1 500
Total of university hospitals	473 432	577 811	576 757	395 969
Region Odense	128 712	150 988	183 430	176 023
Health faculty(9)	68 060	69 312	97 676	122 553
Odense Universitetssygehus	60 652	81 676	85 754	53 470
Total of university hospitals	60 652	81 676	85 754	53 470
Region Aarhus	331 651	347 256	402 840	425 124
Health faculty(9)	195 822	181 081	216 044	246 229
Århus Kommunehospital	43 866	65 563	75 275	79 509
Århus Amtssygehus	26 685	27 354	25 927	28 354
Skejby Sygehus	40 007	48 390	60 161	43 399
Psykiatrisk Hospital i Århus	25 272	24 868	25 432	26 708
Børne og Ungdomspsykiatrisk Hospital(11)	..	..	..	925
Total of university hospitals	135 830	166 175	186 795	178 895
Total in regions	1 244 652	1 372 368	1 498 712	1 277 821
Outside the regions	428 552	525 326	672 520	612 867
Total	**1 673 204**	**1 897 694**	**2 171 232**	**1 890 688**

Table A2b. **Trends in R&D expenditure in health-related public institutions in the three regions**
DKK thousand at current prices

Institution	1991	1993	1995	1 997
Region Copenhagen	713 076	816 607	876 583	676 674
Health faculty(9)	282 632	276 816	322 493	280 705
Copenhagen University Hospital(10)	248 372	306 011	284 147	232 561
Bispebjerg Hospital	18 324	26 834	28 757	25 219
Frederiksberg Hospital	5 211	7 736	8 124	6 345
Amtssygehuset, Herlev	52 549	64 124	84 777	47 596
Hvidovre Hospital	38 738	5 756	81 503	49 200
Amtsygehuset i Gentofte	37 896	29 472	25 485	7 541
Amtssygehuset i Glostrup	17 078	25 371	33 145	26 007
Københavns kommunehospital	12 276	22 737	28 152	1 500
Total of university hospitals	430 444	539 791	554 090	395 969
Region Odense	117 025	141 053	176 221	176 023
Health faculty(9)	61 880	64 751	93 837	122 553
Odense Universitetssygehus	55 145	76 302	82 384	53 470
Total of university hospitals	55 145	76 302	82 384	53 470
Region Aarhus	301 537	324 407	387 008	425 124
Health faculty(9)	178 041	169 166	207 553	246 229
Århus Kommunehospital	39 883	61 249	72 317	79 509
Århus Amtssygehus	24 262	25 554	24 908	28 354
Skejby Sygehus	36 374	45 206	57 797	43 399
Psykiatrisk Hospital i Århus	22 977	23 232	24 433	26 708
Børne og Ungdomspsykiatrisk Hospital(11)	..	..	..	925
Total of university hospitals	123 496	155 241	179 455	178 895
Total in regions	1 131 638	1 282 067	1 439 812	1 277 821
Outside the regions	389 639	490 759	646 090	612 867
Total	**1 521 277**	**1 772 826**	**2 085 902**	**1 890 688**

Table A3a. **Trends in R&D expenditure in health-related public institutions: internal and external funds**
DKK thousand at 1997 prices

Institution	1991		1993		1995		1997	
Source of finance	Internal	External	Internal	External	Internal	External	Internal	External
Universities(1)	442 509	176 460	390 307	200 550	496 901	214 886	475 593	244 666
University of Copenhagen(2)	225 301	85 557	200 862	95 452	235 982	99 703	166 371	114 334
University of Aarhus(2)	129 562	66 259	113 528	67 553	146 951	69 092	180 420	65 809
University of Odense(2)	50 934	17 126	44 038	25 274	75 082	34 478	78 310	44 243
Royal Danish School of Pharmacy	36 711	7 518	31 880	12 271	38 886	11 612	50 492	20 280
Government research institutions	91 258	29 702	164 735	30 984	207 891	71 926	87 003	120 700
Other institutions	130 267	45 085	152 528	47 851	175 281	64 208	202 431	61 761
Hospitals	478 342	279 581	504 903	405 837	511 470	428 669	256 031	442 503
H:S(6)	225 137	142 193	252 368	207 937	241 621	194 660	116 737	205 539
County of Copenhagen(7)	88 151	30 110	94 466	32 881	100 694	48 579	40 455	40 689
County of Frederiksborg(7)	+	+	+	+	+	+	1 768	4 972
County of Roskilde(7)	+	+	+	+	+	+	320	3 592
County of Storstroem	..	..	..	..	..	..	120	2 670
County of Bornholm	..	..	..	..	..	..	0	0
County of Westzealand	..	..	..	..	..	..	2 561	916
County of Funen	40 913	19 739	54 458	27 218	47 093	38 661	17 928	38 059
County of Ribe	..	..	..	..	..	..	1 073	433
County of South Jutland	..	..	..	..	..	..	0	1 303
County of Vejle	..	..	..	..	..	..	3 462	5 800
County of Aarhus	71 185	70 949	55 902	118 454	72 393	124 696	57 593	129 059
County of Viborg	..	..	..	..	..	..	1 285	2 453
County of Ringkoebing	..	..	..	..	..	..	4 075	1 700
County of North Jutland	19 324	3 941	13 556	4 457	14 450	6 623	8 654	5 318
Estimate of smaller hospitals	336 33	12 648	34 152	14 890	35 219	15 449	..	..
Total	**1 142 377**	**530 827**	**1 212 473**	**685 222**	**1 391 542**	**779 689**	**1 021 058**	**869 630**

Table A3b. **Trends in R&D expenditure in health-related public institutions: internal and external funds**
DKK thousand at current prices

Institution	1991		1993		1995		1997	
Source of finance	Internal	External	Internal	External	Internal	External	Internal	External
Universities(1)	402 329	160 437	364 625	187 354	477 373	206 441	475 593	244 666
University of Copenhagen(2)	204 844	77 788	187 645	89 171	226 708	95 785	166 371	114 334
University of Aarhus(2)	117 798	60 243	106 058	63 108	141 176	66 377	180 420	65 809
University of Odense(2)	46 309	15 571	41 140	23 611	72 131	33 123	78 310	44 243
Royal Danish School of Pharmacy	33 378	6 835	29 782	11 464	37 358	11156	50 492	20 280
Government research institutions	82 972	27 005	153 895	28 945	199 721	69 099	87 003	120 700
Other institutions	118 439	40 991	142 492	44 702	168 392	61 685	202 431	61 761
Hospitals	434 909	254 195	471 680	379 133	491 369	411 822	256 031	442 503
H:S(6)	204 695	129 282	235 762	194 255	232 125	187 010	118 737	205 539
County of Copenhagen(7)	80 147	27 376	88 250	30 717	96 737	46 670	40 455	40 689
County of Frederiksborg(7)	+	+	+	+	+	+	1 768	4 972
County of Roskilde(7)	+	+	+	+	+	+	320	3 592
County of Storstroem	..	..	..	..	..	..	120	2 670
County of Bornholm	..	..	..	..	..	..	0	0
County of Westzealand	..	..	..	..	..	..	2 561	916
County of Funen	37 198	17 947	50 875	25 427	45 242	37 142	17 928	38 059
County of Ribe	..	..	..	..	..	..	1 073	433
County of South Jutland	..	..	..	..	..	..	0	1 303
County of Vejle	..	..	..	..	..	..	3 462	5 800
County of Aarhus	64 721	64 507	52 224	110 660	69 548	119 795	57 593	129 059
County of Viborg	..	..	..	..	..	..	1 285	2 453
County of Ringkoebing	..	..	..	..	..	..	4 075	1 700
County of North Jutland	17 569	3 583	12 664	4 164	13 882	6 363	8 654	5 318
Estimate of smaller hospitals	30 579	11 500	31 905	13 910	33 835	14 842	..	..
Total	**1 038 649**	**482 628**	**1 132 692**	**640 134**	**1 336 855**	**749 047**	**1 021 058**	**869 630**

Table A4a. **Public health-related R&D expenditure by field of research**
DKK thousand at 1997 prices

Field of research	1991	1993	1995	1997(14)
Biomedicine	772 543	846 678	958 965	754 712
Clinical medical science	453 613	528 117	586 696	355 187
Social medical science	128 121	116 713	123 129	151 869
Odontology	63 347	74 746	104 975	60 260
Pharmacy, pharmacology	60 276	69 493	91 880	85 822
Other health science	130 509	188 128	233 875	187 794
Other science	64 795	73 820	71 710	..
Total	**1 673 204**	**1 897 694**	**2 171 232**	**1 595 644**

Table A4b. **Public health-related R&D expenditure by field of research**
DKK thousand at current prices

Field of research	1991	1993	1995	1997(14)
Biomedicine	702 396	790 966	921 278	754 712
Clinical medical science	412 425	493 367	563 639	355 187
Social medical science	116 488	109 033	118 290	151 869
Odontology	57 595	69 828	100 850	60 260
Pharmacy, pharmacology	54 803	64 920	88 269	85 822
Other health science	118 659	175 749	224 684	187 794
Other science	58 911	68 963	68 892	..
Total	**1 521 277**	**1 772 826**	**2 085 902**	**1 595 644**

Table A5a. **Trends in R&D expenditure in health-related industries**
DKK thousand at 1997 prices

	1991	1993	1995	1997
Pharmaceuticals	1 465 978	1 531 584	2 132 079	2 655 939
Manufacturing of medico equipment	181 388	140 061	221 104	299 386
Total health-related	1 647 366	1 671 645	2 353 183	2 955 325
Other manufacturing	4 162 311	4 361 828	4 871 800	5 326 726
Total manufacturing firms	**5 809 677**	**6 033 473**	**7 224 983**	**8 282 051**

Table A5b. **Trends in R&D expenditure in health-related industries**
DKK thousand at current prices

	1991	1993	1995	1997
Pharmaceuticals	1 332 867	1 430 806	2 048 288	2 655 939
Medical equipment	164 918	130 845	212 415	299 386
Total health-related	1 497 785	1 561 651	2 260 703	2 955 325
Other manufacturing	3 784 373	4 074 820	4 680 338	5 326 726
Total manufacturing firms	**5 282 158**	**5 636 470**	**6 941 041**	**8 282 051**

Table A6a. **Trends in R&D personnel (head count) employed in health-related public institutions**

Institution	1991	1993	1995	1997
Universities(1)	1 646	1 624	1 649	1 764
University of Copenhagen(2)	799	745	775	741
University of Aarhus(2)	528	511	530	539
University of Odense(2)	192	234	227	293
Royal Danish School of Pharmacy	127	134	117	191
Government research institutions	401	374	477	822
Other institutions	530	525	640	883
Hospitals	5 178	5 529	5 840	4 025
H:S(6)	2 236	2 465	2 489	1 520
County of Copenhagen(7)	801	858	889	788
County of Frederiksborg(7)	+	+	+	25
County of Roskilde(7)	..	..	..	31
County of Storstroem	..	..	..	12
County of Bornholm	..	..	..	0
County of Westzealand	..	..	..	39
County of Funen	519	653	799	379
County of Ribe	..	..	..	29
County of South Jutland	..	..	..	5
County of Vejle	..	..	..	41
County of Aarhus	841	843	935	911
County of Viborg	..	..	..	29
County of Ringkoebing	..	..	..	30
County of North Jutland	238	158	171	186
Estimate of smaller hospitals	543	552	557	..
Total	**7 755**	**8 052**	**8 606**	**7 494**

Table A6b. **Trends in R&D person-years in health-related public institutions**

Institution	1991	1993	1995	1997
Universities(1)	1 060	1 008	1 005	1 192
University of Copenhagen(2)	541	476	463	592
University of Aarhus(2)	348	342	326	323
University of Odense(2)	118	116	147	171
Royal Danish School of Pharmacy	53	74	69	106
Government research institutions	205	277	341	390
Other institutions	327	352	418	584
Hospitals	1 367	1 702	1 825	1 716
H:S(6)	629	828	885	741
County of Copenhagen(7)	193	202	225	205
County of Frederiksborg(7)	+	+	+	17
County of Roskilde(7)	..	..	..	13
County of Storstroem	..	..	..	7
County of Bornholm	..	..	..	0
County of Westzealand	..	..	..	10
County of Funen	119	179	171	149
County of Ribe	..	..	..	4
County of South Jutland	..	..	..	4
County of Vejle	..	..	..	22
County of Aarhus	307	377	416	481
County of Viborg	..	..	..	10
County of Ringkoebing	..	..	..	19
County of North Jutland	38	30	39	34
Estimate of smaller hospitals	81	86	89	..
Total	**2 959**	**3 340**	**3 588**	**3 882**

Table A7a. **Trends in R&D personnel (head count) employed in health-related public institutions, distributed by region**

Institutions	1991	1993	1995	1997
Region Copenhagen	3 771	4 042	4 126	3 020
Health faculty[9]	768	745	775	741
Copenhagen University Hospital[10]	1 653	1 660	1 766	1 018
Bispebjerg Hospital	133	187	161	111
Frederiksberg Hospital	45	111	98	41
Amtssygehuset, Herlev	299	374	400	352
Hvidovre Hospital	307	403	364	309
Amtsygehuset i Gentofte	297	246	255	116
Amtssygehuset i Glostrup	205	238	234	320
Københavns kommunehospital	64	78	73	12
Total of university hospitals	3 003	3 297	3 351	2 279
Region Odense	711	887	1 002	653
Health faculty[9]	192	234	203	293
Odense Universitetssygehus	519	653	799	360
Total of university hospitals	519	653	799	360
Region Aarhus	1 376	1 324	1 428	1 395
Health faculty[9]	565	511	530	539
Århus Kommunehospital	307	333	324	332
Århus Amtssygehus	124	108	153	118
Skejby Sygehus	223	161	181	125
Psykiatrisk Hospital i Århus	157	211	240	276
Børne og Ungdomspsykiatrisk Hospital[11]	..	..	..	5
Total of university hospitals	811	813	898	856
Total in regions	5 858	6 253	6 556	5 068
Outside the regions	1 897	1 799	2 050	2 426
Total	**7 755**	**8 052**	**8 606**	**7 494**

Table A7b. **Trends in R&D person years in health-related public institutions**

Institutions	1991	1993	1995	1997
Region Copenhagen	1 325	1 486	1 555	1 518
Health faculty(9)	529	476	463	592
Copenhagen University Hospital(10)	430	556	598	500
Bispebjerg Hospital	46	50	60	64
Frederiksberg Hospital	9	16	18	22
Amtssygehuset, Herlev	83	96	121	108
Hvidovre Hospital	87	130	128	127
Amtsygehuset i Gentofte	60	47	44	25
Amtssygehuset i Glostrup	49	59	59	71
Københavns kommunehospital	32	57	63	9
Total of university hospitals	796	1 010	1 092	926
Region Odense	237	295	298	313
Health faculty(9)	118	116	127	171
Odense Universitetssygehus	119	179	171	142
Total of university hospitals	119	179	171	142
Region Aarhus	638	696	717	773
Health faculty(9)	350	342	326	323
Århus Kommune hospital	94	144	167	197
Århus Amtssygehus	56	69	68	95
Skejby Sygehus	83	85	94	75
Psykiatrisk Hospital i Århus	56	55	61	79
Børne og Ungdomspsykiatrisk Hospital(11)	..	..	..	4
Total of university hospitals	288	354	391	450
Total in regions	2 200	2 476	2 570	2 604
Outside the regions	759	864	1 018	1 278
Total	**2 959**	**3 340**	**3 588**	**3 882**

Table A8. **Trends in number of persons engaged in R&D (head count) per person year on R&D in health-related public institutions, by region**

Institutions	1991	1993	1995	1997
Region Copenhagen	2.85	2.72	2.65	1.99
Health faculty[9]	1.45	1.57	1.67	1.25
Copenhagen University Hospital[10]	3.84	2.99	2.95	2.04
Bispebjerg Hospital	2.89	3.74	2.68	1.73
Frederiksberg Hospital	5.00	6.94	5.44	1.86
Amtssygehuset, Herlev	3.60	3.90	3.31	3.25
Hvidovre Hospital	3.53	3.10	2.84	2.43
Amtsygehuset i Gentofte	4.95	5.23	5.80	4.64
Amtssygehuset i Glostrup	4.18	4.03	3.97	4.51
Københavns kommunehospital	2.00	1.37	1.16	1.33
Total of university hospitals	3.77	3.26	3.07	2.46
Region Odense	3.00	3.01	3.36	2.09
Health faculty[9]	1.63	2.02	1.60	1.71
Odense Universitetssygehus	4.36	3.65	4.67	2.54
Total of university hospitals	4.36	3.65	4.67	2.54
Region Aarhus	2.16	1.90	1.99	1.80
Health faculty[9]	1.61	1.49	1.62	1.67
Århus Kommunehospital	3.27	2.31	1.94	1.69
Århus Amtssygehus	2.21	1.57	2.25	1.24
Skejby Sygehus	2.69	1.89	1.93	1.67
Psykiatrisk Hospital i Århus	2.80	3.84	3.93	3.49
Børne og Ungdomspsykiatrisk Hospital[11]	..	..	..	1.25
Total of university hospitals	2.82	2.30	2.30	1.90
Total in regions	2.66	2.53	2.55	1.95
Outside the regions	2.50	2.08	2.01	1.90
Total	**2.62**	**2.41**	**2.40**	**1.93**

Table A9a. **Trends in R&D personnel in the health-related industries in the business enterprise sector**

	1991	1993	1995	1997
Pharmaceuticals	2 809	3 157	3 451	3 123
Medical equipment	417	362	391	560
Total health-related	3 226	3 519	3 842	3 683
Other manufacturing	11 733	10 351	10 824	11 394
Total manufacturing firms	**14 959**	**13 870**	**14 666**	**15 077**

Table A9b. **Trends in R&D person years in the health-related industries in the business enterprise sector**

	1991	1993	1995	1997
Pharmaceuticals	2 616	2 997	3 304	2 934
Medical equipment	335	298	350	458
Total health-related	2 951	3 294	3 654	3 392
Other manufacturing	8 081	7 627	8 071	8 271
Total manufacturing firms	**11 032**	**10 921**	**11 725**	**11 663**

Table A10a. **Trends in R&D personnel (head count) employed in health-related public institutions, by field of research**

Field of research	1991	1993	1995	1997[14]
Biomedicine	3 024	2 634	3 014	2 595
Clinical medical science	2 737	3 340	3 516	2 117
Social medical science	458	428	333	533
Odontology	207	248	217	243
Pharmacy, pharmacology	231	235	259	322
Other health science	846	956	1 106	567
Other science	251	211	162	++
Total	**7 754**	**8 052**	**8 607**	**6 377**

Table A10b. **Trends in R&D person-years employed in health-related public institutions, by field of research**

Field of research	1991	1993	1995	1997(14)
Biomedicine	1 357	1 448	1 571	1 468
Clinical medical science	806	983	1 057	755
Social medical science	233	215	186	268
Odontology	100	124	127	113
Pharmacy, pharmacology	105	145	151	194
Other health science	231	323	394	345
Other science	127	102	102	++
Total	**2 959**	**3 340**	**3 588**	**3 143**

Table A11. **Person years worked on R&D in hospitals, by field of research – 1997(14)**

Field of research	Biomedicine & biotechnology	Research in treatment	Neurology & psychiatry	Preventive health	Work medicine	Social medicine	Gerontology	Information technology
Hospitals								
H:S(8)	92	43	43	40	4	1	14	4
County of Copenhagen(7)	93	48	5	34	4	6	2	4
County of Frederiksborg(7)	5	0	5	1	2	0	0	0
County of Roskilde(7)	5	1	1	3	0	0	0	0
County of Storstroem	4	0	1	1	0	0	2	0
County of Bornholm	0	0	0	0	0	0	0	0
County of Westzealand	4	2	2	1	0	0	0	0
County of Funen	46	16	12	57	5	3	5	2
County of Ribe	0	2	0	0	0	2	0	0
County of South Jutland	0	0	0	4	0	0	0	0
County of Vejle	5	6	0	7	2	0	0	1
County of Aarhus	185	50	91	96	0	2	8	6
County of Viborg	2	2	0	2	4	0	0	0
County of Ringkoebing	3	3	0	0	12	0	0	0
County of North Jutland	21	3	3	4	0	0	2	1
Total	**465**	**176**	**163**	**250**	**33**	**14**	**33**	**18**

Table A12a. **Trends in the number of head doctors/professors working on R&D in hospitals and universities (head count)**

Institutions	1991	1993	1995	1997
Region Copenhagen	387	438	405	446
Health faculty(9)	40	31	35	49
Copenhagen University Hospital(10)	137	123	127	164
Bispebjerg Hospital	27	48	22	14
Frederiksberg Hospital	14	28	24	11
Amtssygehuset, Herlev	47	61	61	78
Hvidovre Hospital	47	66	52	41
Amtsygehuset i Gentofte	32	37	42	27
Amtssygehuset i Glostrup	34	38	34	61
Københavns kommunehospital	9	6	8	1
Total of university hospitals	347	407	370	397
Region Odense	114	122	141	152
Health faculty(9)	10	12	26	45
Odense Universitetssygehus	104	110	115	107
Total of university hospitals	104	110	115	107
Region Aarhus	157	149	159	194
Health faculty(9)	22	23	21	36
Århus Kommunehospital	51	59	56	76
Århus Amtssygehus	14	11	19	22
Skejby Sygehus	38	21	27	15
Psykiatrisk Hospital i Århus	32	35	36	44
Børne og Ungdomspsykiatrisk Hospital(11)	..	..	..	1
Total of university hospitals	135	126	138	158
Total in regions	658	709	705	792
Outside the regions	233	217	239	232
Total	**891**	**926**	**944**	**1 024**

Table A12b. **Trends in the number of person years spent on R&D by head doctors/professors in hospitals and universities**

Institutions	1991	1993	1995	1997
Region Copenhagen	84	82	96	119
Health faculty[9]	20	13	17	27
Copenhagen University Hospital[10]	28	19	28	47
Bispebjerg Hospital	4	8	6	3
Frederiksberg Hospital	2	2	2	2
Amtssygehuset, Herlev	10	11	15	15
Hvidovre Hospital	7	15	10	14
Amtsygehuset i Gentofte	5	5	5	4
Amtssygehuset i Glostrup	3	4	5	7
Københavns kommunehospital	5	5	8	0
Total of university hospitals	64	69	79	92
Region Odense	22	25	27	34
Health faculty[9]	5	6	9	16
Odense Universitetssygehus	17	19	19	18
Total of university hospitals	17	19	19	18
Region Aarhus	44	33	33	65
Health faculty[9]	20	13	12	18
Århus Kommunehospital	9	11	11	21
Århus Amtssygehus	2	2	2	12
Skejby Sygehus	7	4	5	5
Psykiatrisk Hospital I Århus	6	3	3	8
Børne og Ungdomspsykiatrisk Hospital[11]	..	..	..	1
Total of university hospitals	24	20	21	47
Total in regions	150	140	157	218
Outside the regions	38	49	47	81
Total	**188**	**189**	**204**	**299**

Table A13a. **Trends in R&D personnel (head count) in hospitals by category/position**

Personnel categories	1991		1993		1995		1997	
	Personnel	Women (%)	Personnel	Women (%)	Personnel	Women (%)	Personnel	Women (%)
Head doctor/professor	643	12	682	11	677	13	768	16
Head of department	..	..	..	..	220	30	310	28
Secondary doctor (reserve)	1 542	30	1 450	36	1 120	35	753	39
Clinical assistant/senior researcher	68	31	114	33	240	35	385	54
Other scientific personnel	511	32	533	35	459	37	571	47
Nurse	..	.	..	..	..	..	518	88
Technical-adm. staff	..	..	..	..	..	..	720	82
Nurse/technical-adm. staff	1 736	81	1863	91	2 123	89	..	..
PhD student	135	27	335	39	444	41	513	45..
Total	**4 635**	**47**	**4 977**	**53**	**5 283**	**54**	**4 025**	**50**

Table A13b. **Trends in R&D person years in the hospitals by employment category/position**

Personnel categories	1991		1993		1995		1997	
	Personnel	Women (%)	Personnel	Women (%)	Personnel	Women (%)	Personnel	Women (%)
Head doctor/professor	114	..	114	..	125	..	173	13
Head of department	..	..	..	..	28		72	33
Secondary doctor (reserve)	166	..	158	..	113	..	151	37
Clinical assistant/senior researcher	62	..	95	..	195		343	55
Other scientific personnel	306	..	321	..	244	..	383	44
Nurse	..	..	..	..	..		193	88
Technical-adm. staff	..	..	..	..	..	..	392	83
Nurse/technical-adm. staff	526	..	645	..	647		..	..
Residual person years	..	..	..	..	..	..	9	94
PhD student	111	..	283	..	383		..	..
Total	**1 285**	**..**	**1 617**	**..**	**1 735**	**..**	**1 716**	**56**

Annex 3

IMPACT OF THE NEW 1997 SURVEY METHODS ON APPARENT TRENDS IN R&D FUNDING AND PERSONNEL IN HOSPITALS

A significant amount of the R&D carried out in the Danish public health sector is conducted in the hospitals. Information about R&D in the largest hospitals has traditionally been collected as a part of the data used for the R&D statistical report on the public sector. In the latest statistical R&D report, there was a special survey of all hospitals in Denmark. This is rare because usually estimates are made for R&D activity in the smaller hospitals (*Forskning and udviklingsarbejde i den offentlige sektor – Forsknings-statistik* 1995, published by The Danish Ministry of Research and Technology, August 1997).

Every ten years, a so-called "total count" is made of R&D carried out in the Danish hospitals. 1997 was such a year. In 1997, a different method of calculation was used to measure R&D in the hospitals compared to that used in earlier years. This Annex identifies and accounts for the differences between the 1995 and 1997 statistical reports.

The data collection process: 1997 compared to 1995 and earlier surveys

The questionnaire used in 1997 was designed by the Danish Institute for Studies in Research and Research Policy (referred to as the Institute) together with the Ministry of Health. It included all the questions underlying the statistics published in the public sector R&D report. This survey differed from earlier statistical reports, where many of the published statistics were calculations based on information about person-years devoted to R&D. This Annex describes the differences in method of calculation. It presents estimates of how large the differences in R&D expenditure between 1995 and 1997 would have been if the method of calculation based on person-years used in 1995 and earlier had been used in 1997.

In the collection of data for 1997, all information about R&D expenditures was obtained via a questionnaire in which the source of funds also had to be reported. Calculations for 1997 are based on information received from the individual hospitals; this information was subsequently returned to them for approval.

Unlike in 1997, reports on public sector R&D in 1995 and in earlier volumes, the internally financed R&D expenditure was calculated on the basis of different distribution methods. The basis for the 1995 calculations of the different types of expenditure was the person-years reported by the different departments in the hospitals.

The internally financed expenditure calculated in 1995 was based on the average salaries for the different personnel categories. These average salaries were then multiplied by the total person-years in the different categories for which there was information.

Expenditure on equipment in 1995 was calculated as 3% of total internally financed expenditure unless the individual hospital had stated otherwise or had specified this expenditure.

Other internally financed expenditure in 1995 was, as a general rule, calculated as 65% of total internally financed expenditure. To this were added building expenditure, calculated on the basis of keys of distribution that varied from hospital to hospital. In some hospitals, more information was available on the R&D share of the common expenditure and this was incorporated into other internally financed expenditure. This meant that total internally financed expenditure for some institutions was larger than 65%.

These three categories of expenditure were added together to provide total internally financed expenditure on R&D in 1995. The same method was used in 1993.

The 1997 expenditure estimated by the method used in 1995

In order to test the results of the changes made between 1995 and 1997, the Institute estimated what the result in 1997 would have been if the 1995 method had been used. This means using the same factors and applying them to the person-years for 1997.

If expenditure on salaries had been calculated using average salaries (taken from the "*overenskomststatistik for den offentlige sektor*, 1997"), the calculations show that the figure for 1997 would have been DKK 605 million. Actual reported salary expenditures for 1997 were DKK 524 million. This represents an increase of DKK 81 million, compared with the calculations made using the 1995 method. There is no ready explanation for the difference between the reported and calculated salary expenditures and there is no reason to consider that the reported information is incorrect. There is also no reason to doubt the reported information on the R&D person-years, although the information on person-years compared with the personnel in the hospitals for 1997 might indicate that less person-years were used than reported.

If internally financed expenditure on equipment for 1997 had been calculated using the 1995 method, it would have amounted to around DKK 6 million. In 1997, these expenditures were reported to be DKK 9 million. All in all, a change in the calculation method would lead to a decrease of DKK 3 million in internally financed equipment expenditure. There is no reason to assume that the reported equipment expenditures are less accurate than they would have been if estimated using the 1995 method.

If other internally financed expenditure in 1997 had been calculated following the method used in 1995, total other internally financed expenditure would be around DKK 163 million. The number reported for 1997 is DKK 36 million, *i.e.* a difference of DKK 127 million. Applying the principles used in the 1995 statistical report would give a significantly larger figure for expenditure. Because the numbers reported for 1997 were returned to the management in the various hospitals for approval, there is no reason to assume that the estimations were more accurate than those published in the 1997 statistical report.

Altogether, if the calculation of internally financed expenditure in 1997 were carried out using the same method as in 1995, this would mean that internally financed expenditure in the hospitals would represent DKK 205 million (DKK 81 million – DKK 3 million + DKK 127 million) more than the amount published in this report. In this report, the decline is measured as DKK 241 million in 1997 prices in the period 1995-97. Compared to this number, the calculation method used in 1995 on the data from 1997 can explain 85% of the decline. There is no reason to believe that the calculation method is more correct than the reported data. Although some hospitals have not provided information on "other internally financed expenditure", this is likely to have only a minimal impact on total internally financed expenditure.

Closing remarks

Because of the numbers mentioned in this Annex and since the calculations of the different numbers show different results, the reader should be very careful about making detailed conclusions based on data shown in this report and should bear this in mind when in comparing the numbers for 1991-97. It should also be noted, as mentioned in the conclusion to this report, that the reported data indicate a decline in total person-years in the period 1995-97 (as illustrated in the tables), while there has been an even more significant decline in the total numbers of personnel employed on R&D from 1995 to 1997. These numbers have not been corrected because the data collection method concerning the number of personnel and person-years has remained the same throughout the period.

Information on externally financed R&D expenditure has been reported by the hospitals in all the survey years. In the 1997 survey, these data were collected using a matrix in which expenditure and sources of funds had to match. This method may have had a positive influence on the responses, and can only lead to an improved and more robust statistical report.

Last but not least, it should be added that the Institute believes that it is better to receive data directly from the institutions rather than relying on calculations based on the reported number of person-years. We believe that the statistical report thereby provides a more valid and better tool with which to evaluate R&D in the health sector. However, this conclusion assumes that administration at the Danish hospitals and their counterparts in other OECD countries are able to provide accurate figures. The validity of that assumption might usefully be discussed at an international forum such as the OECD's NESTI workshop on measuring health R&D.

Chapter 9

ESTIMATING HEALTH-RELATED R&D EXPENDITURE IN FRANCE

by

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This chapter was prepared specially to contribute French experience to the discussion of the problems of measuring heath R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in France. An extended and updated version in French will be published shortly.[1]

The aim of this chapter is to estimate the amount of R&D activity in health and the life sciences in the various sectors of performance and to sum them to calculate health-related GERD and health-related GNERD.[2] This exercise involved drawing on a range of R&D surveys. It has allowed us to obtain an initial picture of health-related R&D in the public and private sectors but has also revealed a number of gaps and grey areas, some resulting from the way research is organised in France and others from our survey methods.

These results are experimental and are intended as the basis for further discussion.

Identifying the actors in health-related research in the public sector

The main actors

The public sector in the French system and national publications covers the *Frascati Manual* Government, Higher Education and PNP sectors. Within this, health R&D centres round three poles:

- Government agencies, notably the National Institute for Health and Medical Research (INSERM) and the National Council for Scientific Research (CNRS), especially its life sciences department.

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[1] "Les dépenses de R-D en santé en France en 1998", in *Education et formation*, the quarterly review published by la Direction de la programmation et du développement du Ministère de l'Education nationale.

[2] GERD measures R&D carried out on national territory. GNERD measures R&D financed by the country concerned. It is equal to GERD minus funds from abroad, plus extramural funds to abroad.

- University Hospital Centres (CHU), of which there are 29, and Centres for the Fight against Cancer (CLCC), which are also hospital organisations but have private status. The best known are the Curie Institute and the Gustave Roussy Institute.

- Associations, notably the Pasteur Institutes and the Human Genome Research Centre financed by the French Muscular Dystrophy Association.

These actors are closely linked by means of joint laboratories. For example, most INSERM laboratories are situated at University Hospital Centres or universities. Teaching is a common function for the staff.

The Minister for Research is in charge of the government research agencies. In the case of INSERM, responsibility is shared with the Minister for Health.

Identifying the resources for health-related R&D

- The annual survey of the socio-economic objectives of government civil R&D funding was used to identify the actors.

- Two categories were chosen: "health" and "advancement of knowledge – life sciences" (the French SEO classification does not distinguish between human, animal and vegetable life sciences under advancement of knowledge). These two categories were chosen because they cover the relevant R&D of the two largest agencies involved: INSERM mainly in "health", and the CNRS in "advancement of knowledge".

- The optimal approach would be to work at the level of the activities within the agencies, which may involve different patterns of funding. However, data are not available at that level.

- Consequently, the data have been established by calculating these two areas as a percentage of total government R&D budget received by each agency and then applying this to the other variables collected in the survey concerning expenditure, sources of funds and personnel.

- For the universities, the health share was estimated by taking the percentage of "hospital-university" staff in total university researchers and applying it to total R&D expenditure. This category of staff combines the functions of doctor, researcher and research/teacher. They have two employers: the universities for their teaching and research activities; and hospitals for health care. This calculation does not make any allowance for research in the life sciences by teachers/researchers who do not have this special status. This would require basic data which crossed employment categories with field of science.

- In recent years, we have improved our range of surveys by adding one of "associations" (40% of which are estimated to be active in the area of health) and another of clinical research in university hospitals.

- Combining the results from these surveys gives the following tables. In the French system data is collected on total R&D expenditure (intramural + extramural) broken down by source of funds (Table 9.1) and by performer/destination (Table 9.2). An exercise is undertaken to match extramural payments to receipts. In 1997, 17% of the R&D expenditure in the public sector was health-related.

Table 9.1. **Total expenditure on public sector health-related R&D in France, by principal sector and by source of funds – 1997**

	Budget	Own funds	Outside sources						"Budget"
			From government	From HE	From PNP	From BE	From abroad	**Total**	**Grand total**
Government	3 736	188	171	8	38	157	90	**465**	**4 388**
HES	5 155	182	451	11	25	153	126	**767**	**6 104**
Hospitals[1]	656		146	2	70	75	18	**310**	**967**
PNP	357	728	147	41	76	222	107	**594**	**1 679**
Total	**9 905**	**1 097**	**915**	**62**	**209**	**607**	**365**	**2 136**	**13 138**

1. Including CLCC.
Source: Ministère de l'Éducation nationale, DPD-C3.

Table 9.2. **Total expenditure on public sector health-related R&D in France, by main sector and by sector of destination – 1997**

	Intramural	Extramural						"Budget"
	TOTAL	To government	To HE	To PNP	To BE	To abroad	**Total**	**Grand total**
Government	**3 297**	145	547	51	216	132	**1 091**	**4 388**
HES	**5 964**	36	16	17	6	65	**140**	**6 104**
Hospitals	**953**	3	3	5	1	3	**14**	**967**
PNP	**1 468**	38	89	9	26	48	**211**	**1 679**
Total	**11 683**	**222**	**655**	**82**	**249**	**247**	**1 456**	13 138
Total public	**68 211**						**25 787**	**93 998**
% health	**17%**							**14%**

1. Including CLCC.
Source: Ministère de l'Éducation nationale, DPD-C3.

- Thanks to the survey of clinical research, it has been possible to make some first estimates of clinical research in university hospitals based on a specially designed questionnaire. The problems are the same as those already encountered for the universities. With the exception of one or two specific schemes (such as the hospital clinical research programme), hospital budgets, like university ones, do not distinguish between health care, teaching and research. In consequence, the research contribution of the hospitals is under-estimated because of the problem of estimating the time spent by personnel with three functions (research, education and care) and two employers. For the same reasons, in the absence of a suitable accounting system, it is difficult to evaluate the hospital contribution to R&D in laboratories on hospital sites.

- The recent move to recognise the research role of hospitals, embodied in the clinical research law/regulations, should encourage better measurement of the resources involved. We have chosen to base our calculations on the number of protocols. Possible alternatives include the number of patients or even the number of publications.

- The survey of the associations allows the identification of the role of foundations and charities in direct funding of health-related research, whether in the form of fellowships or grants to laboratories financed by donations and legacies. The problems involved in measuring the indirect costs to the host organisations induced by the resulting activities need to be solved for both universities and hospitals. The associations also act as intermediaries in the flow of funds for health-related R&D.

- The results show that associations may also be R&D performers. Some associations run serious research centres, such as the Human Genome Research Centre financed by the French Muscular Dystrophy Association.

Results of the survey of pharmaceutical enterprises

The initial hypothesis here is that all R&D in the pharmaceutical and medical equipment industries is health-related (about 13% of BERD).

Table 9.3. **Total R&D expenditure by the pharmaceutical and medical equipment industries– 1997**

	1997
Intramural expenditure	15 091
Extramural expenditure	2 831
of which:	
To performers in France[1]	1 445
To abroad	1 386
Total expenditure	**17 922**
Pharmaceutical GNERD	15 605

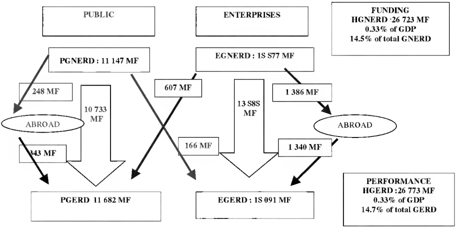
1. Extramural R&D to other French performers outside the pharmaceutical and medical supplies industry. Needed to calculate the total domestic R&D budget of the industry.
Source: Ministère de l'Éducation nationale, DPC-C3.

Consolidating the flows between the sectors: What do we learn?

A health-related GERD and a health-related GNERD have been calculated for 1997, using the standard method of consolidating data from the different surveys. The resulting health-related GERD corresponds to 0.33% of the GDP and 14% of total GERD.

Figure 9.1 illustrates the relative size of the different sectors as funders and performers of health-related R&D.

Figure 9.1. **Relative size of the different sectors as funders and performers of health-related R&D**



Source: Ministère de l'Éducation nationale, DPD-C3.

- Figure 9.1 shows the flows of funds between industry and the public sectors. The payments from government to industry for health-related R&D are lower compared with the situation for total GERD, whereas those from industry to the public sector are about average.

- In the case of the low flows of research funds from government to the pharmaceutical industry, it should be borne in mind that demand for drugs and medicines is only financially viable because of the contribution of social security funds. This might be seen as a form of indirect public support via prices.

- The flow from industry to the public sector is average overall (4% of health-related GNERD). The figures involved do not appear very large; this is partly due to the way in which clinical trials are financed in France. Clinical trials are mainly carried out in university hospitals and the company concerned has to provide the drugs free of charge to the investigators and thus to the hospital. This represents a flow of quantity which is not matched by any flow in value. This cost is included in the intramural R&D expenditure of the industry, leading to an apparent transfer of where the R&D is carried out and leading to an abnormally high share of other current costs. Furthermore, although the companies are billed for the additional direct costs of the trials, they are not charged for time spent or use of technical facilities. The figures are low because charges are calculated on the basis of marginal costs rather than full costs.

- The relative roles of the public and private sectors in health-related research are different when measured in terms of personnel rather than expenditure. Some 29 000 persons work on health-related R&D in the public sector, compared with 18 000 in the pharmaceutical industry (although the latter has higher spending). This calls for two remarks: first, the structure of the R&D labour force varies between the two sectors (34% of researchers in the pharmaceutical industry compared with 49% in the public sector excluding fellows, of which there are about 3 000); second, as indicated above, there is an abnormally large amount of other current costs in the industry. We know that additional payments are made to doctors and their associations, but the amounts are not known. It is assumed that these payments are included in other current costs. The difference in terms of personnel and expenditure might also be linked to their contributions at different stages in the R&D process.

- Figure 9.1 also shows that the flows of funds to and from abroad largely concern the pharmaceutical industry. These flows mainly occur within multinational corporations. As measured here, these only cover payments for R&D services rendered and not financial investments, often used as a means of global restructuring.

Chapter 10

MEASURING RESOURCES DEVOTED TO HEALTH-RELATED R&D IN ISRAEL

by

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This chapter was prepared specially to contribute Israeli experience to the discussion of the problems of measuring heath R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in Israel.

National expenditure on health services in Israel has been measured by the Central Bureau of Statistics since 1962 as satellite accounts to the national accounts. Part of the expenditure on health-related R&D is included in this expenditure; separately-funded R&D carried out in non-market institutions is shown as a separate item.

National expenditure on R&D has been measured by the Central Bureau of Statistics since 1989, also as satellite accounts to the national accounts. Before that (in the1970s and 1980s), some estimates of expenditure on R&D were prepared by the Science Ministry. So far, total health-related R&D has not been published separately, but from this year onwards (2000), it is planned to publish data on expenditure on health-related R&D both in the publication on R&D expenditure and in that on health expenditure.

According to very rough estimates, health-related R&D is estimated to be about 16% of total civilian R&D in Israel. Health-related R&D in the non-market system is by far the most important component, reaching about 74% of total health-related R&D.

The characteristics of the health science and innovation system in Israel and the methods of measuring health-related R&D are described below.

The national health science and innovation system

The non-market system

About three-quarters of health services in Israel are provided by the non-market system. Most of the institutions providing health services also engage in R&D. In addition, health-related R&D is carried out in higher education institutions and in non-profit R&D institutions.

Four main groups of institutions perform R&D:

- *Higher education institutions*. There are four medical schools in the universities – the most important ones being situated at the Hebrew University and Tel Aviv University, although health-related R&D is also carried out at other faculties at universities. This group of institutions also includes the Weizmann Institute – as, although the major part of its expenditure is on R&D, it also functions as a higher education institution.

- *Hospitals*, some of which are associated with universities. The largest part of R&D is conducted at the Hadassah Medical Centre and at hospitals associated with Tel Aviv University. Some of the hospitals are private non-profit institutions, others belong to the general government sector. Some of the personnel employed at the hospitals are also employed by the universities, which can complicate analysis of R&D expenditure.

- *Other health institutions* in the general government or the non-profit institutional sectors.

- *Non-profit institutions* engaging in R&D such as the Joint Distribution Committee.

The funding of non-market R&D comes from various sources:

- Sources in the central government:
  - The Chief Scientist's office at the Health Ministry.
  - The Ministry of Science.
  - General University Funds.
- Other non-profit institutions:
  - The National Academy of Sciences.
  - The Israel Cancer Society.
- Bi-national funds:
  - The US-Israel Bi-national Fund.
  - The German-Israeli Foundation for Scientific Research and Development.
- Sources abroad:
  - Israel Cancer Research Fund (United States).
  - National Institutes of Health (United States).
- General budget of institutions.

Since 1995, a basket of health services is provided to all residents in Israel. These services are provided by four sick funds, which also purchase some of the services from other non-profit institutions. The services are financed by a health tax plus funding from the general budget of the central government. Many of the institutions involved in providing health services also perform some R&D, which is funded from their general budgets. In universities, health-related R&D may also be financed by the general budget.

The main demand for data on health-related R&D comes from the funding bodies. The Chief Scientist's office in the Health Ministry has expressed considerable interest in obtaining more detailed data on expenditure on health-related R&D. A database has been set up with details on health researchers and distribution of types of funding (for a brief description of this database, see Annex 1).

Representatives of the Science Ministry and of the office of the Chief Scientist at the Ministry of Commerce and Manufacturing have also expressed interest in the subject.

The market system

Market health services account for about a quarter of all health services provided in Israel and include services of private hospitals, clinics, dentists, surgeons, and alternative medicine. In addition, there are a number of large pharmaceutical enterprises in Israel with branches abroad, as well as some enterprises producing medical tools and health equipment.

Health-related R&D in the market system is mainly conducted in the pharmaceutical enterprises and in the enterprises producing medical equipment. The R&D in these enterprises is financed by own funds of the enterprises and by funds received from the Chief Scientist's office of the Ministry of Commerce and Manufacturing. If the R&D is successful, the enterprises are required to pay back part of the funds received for R&D from the Ministry of Commerce and Manufacturing.

Health-related R&D is also carried out in some of the many start-ups established in Israel in recent years. Demand from the market system for data on health-related R&D has not been checked.

Table 10.1. **Performance and finance of health-related R&D**

	Performing R&D				
Financing health-related R&D	Universities	Hospitals	Health institutions in general government (excl. hospitals)	Private non-profit institutions (excl. hospitals)	Private enterprises
Chief Scientist, Health Ministry	X	X	X	X	
Chief Scientist, Ministry of Commerce and Manufacturing					X
General University Funds	X				
National Academy of Sciences	X	X	X	X	
Israel Cancer Society	X	X	X	X	
Bi-national Funds	X	X	X	X	
Sources abroad	X	X	X	X	
General budget	X	X	X	X	
Own funds					X

Measuring health related R&D in the non-market/public sector

Data on expenditure on R&D are collected from the institutions performing or financing the R&D, and the data are combined in a matrix form by performing and financing sector. In some cases, data collected from the performing and the financing institutions on a given flow differ – in such cases the reliability of the data is examined, the cause for the difference is sought and one of the figures is chosen.

Since data already are collected for the purpose of estimating health expenditure, R&D expenditure can be located therein and readily identified as health-related R&D. There is, however, an important difference between health expenditure estimates and R&D expenditure estimates: health expenditure estimates are prepared according to the system of national accounts (SNA) and include the value of consumption of fixed capital; R&D expenditure estimates, on the other hand, should be prepared according to the *Frascati Manual* and, thus, should not include the value of consumption of fixed capital. In addition, some health-related basic research carried out in non-market institutions is not covered in the health expenditure estimates and has to be collected independently.

The expenditure data are classified according to SNA type of cost: compensation of employees, intermediate consumption expenditure, capital formation, current transfers, capital transfers.

So far, detailed classifications by type of research have not been added. However, the plan is to adopt the classifications used by the Chief Scientist at the Health Ministry with some modifications, since not all financial data will have the necessary breakdowns. These detailed classifications, which are shown in Annex 1, include four dimensions: research area, organic specific diseases, clinical categories and methodological approach. The data on source of funds is classified according to sector. Following a recommendation from the Chief Scientist's office at the Health Ministry, it is planned to attempt to add a breakdown of funds between peer-reviewed funding and other funding.

Data on expenditure on R&D in the central government are collected from each relevant government ministry. Detailed budget items (eight-digits) are analysed to find the relevant items, and information about the R&D content is gathered from Ministry staff. Contact with these persons has recently been formalised and each Ministry now receives a questionnaire.

Data on expenditure on R&D in universities are collected for two components:

- *R&D financed by R&D funds.* Information on operating expenses for each project is available from detailed financial reports, and the persons responsible for the projects are consulted about the R&D content.
- *R&D financed by general funds.* A survey on work hours spent on R&D was undertaken in 1999, and the results will be used to estimate health-related R&D expenditure in the future. Current estimates are based on coefficients obtained from a survey conducted more than 20 years ago.

R&D carried out in the scientific fields of medicine and para-medical courses can easily be included. However, it should also be possible to identify individual health-related projects in related fields, such as biology, which are financed by R&D funds.

Data on expenditure on health-related R&D in hospitals also have two components:

- *Health-related R&D funded by R&D funds.* Information on operating expenses is obtained from detailed financial reports. So far, the persons responsible for the projects have not been consulted about R&D content. It is planned to do so as of this year.

- *Health-related R&D funded by general hospital funds.* So far, estimates have been made based on data prepared in 1987 by combining data from a special survey on work of persons with academic qualifications and financial data on expenditure at hospitals. At the time of writing, questionnaires to hospital employees and to heads of departments on work hours spent on R&D are being prepared (see Annex 2). In line with the recommendations of the Chief Scientist of the Health Ministry, it is planned to send the questionnaires to a sample of hospital employees and not to rely solely on reports from heads of departments, which might be affected by policy considerations. The questionnaires allow hours spent to be linked to budgets, so that it will be possible to estimate expenditure.

So far, R&D in hospital departments associated with universities has not been added to R&D in higher education. Only when further information has been gathered, will it be possible to do so.

Data on expenditure in non-profit institutions conducting health R&D: an annual NPI survey is conducted to obtain financial data and data on personnel (in FTEs) in these institutions. The questionnaire for this survey is currently being updated to include questions on type of research and type of personnel.

Measuring health-related R&D in the market/industry sector

R&D in the market system is measured in special surveys. The unit of investigation in these surveys is the establishment. Establishments are classified according to the Israeli Standard Industrial Classification, which is based on ISIC 1987 (Rev. 3). Health-related R&D may be identified in the various industries according to the main activity of the industry.

The relevant activities identified are:

- Manufacture of pharmaceutical products for human and veterinary uses (corresponds to ISIC 2423).

- Manufacture of medical and surgical equipment (corresponds to ISIC 3311.1).

- Manufacture of disposable medical equipment (corresponds to ISIC 3311.3).

- Manufacture of medical equipment and orthopaedic articles (corresponds to ISIC 3311.2).

Health-related GERD

Estimates of health-related R&D have not been published separately in Israel to date. However, once additional details have been collected and relevant items broken out of national expenditures on R&D, it will be possible to prepare some preliminary estimates of such expenditures in 1996. These estimates do not include health-related R&D carried out by the army medical corps (this part may not be very significant and we hope to include it in the future) and it is not possible to give very detailed classifications of research area at this stage. As mentioned above, R&D in hospital departments associated with universities has not been included in the R&D in higher education (further information is needed to separate the relevant parts).

Table 10.2. **Preliminary estimate of total expenditure on health-related R&D by sector – 1996**
NIS million

	Total	General government		Higher education	Private non-profit institutions	Business
		Total	*Of which:* sick funds			
Total	1.165	337	133	197	323	308
Hospitals total:	637	305	133	-	295	37
Hospitals general budget	393	284	114	-	72	37
Hospitals: special R&D funds	244	21	19	-		
Other R&D	528	32	-	197	28	271

Source: Central Bureau of Statistics.

For this exercise, only the expenditure was identified. In order to prepare the full account on health-related R&D, we need to add data on source of funds by sector. Data on the percentage of researchers receiving finance from external funds are shown below.

We have not prepared data on personnel for this exercise, but the survey conducted by the Chief Scientist's office at the Health Ministry (described in Annex 1) provides a picture of researchers engaged in health-related R&D. This survey shows that in 1998, close to 60% of health researchers were employed at hospitals and about 40% at non-hospital institutions. Some 55% of the researchers have a medical degree, and 45% a non-medical degree; 70% of researchers receive external funding while 61% receive funding from abroad.

Table10.3. **External funding of health-related R&D – 1998**

Fund	Percentage of researchers receiving finance from the funds
Total external funds	70%
Chief Scientist, Ministry of Health	40%
US-Israel Bi-national Science Fund	17%
National Academy of Sciences	11%
Ministry of Science	10%
Israel Cancer Society	9%
Israel Cancer Research Fund (USA)	9%
German-Israeli Fund for Scientific Research and Development	8%
National Institute of Health (United States) and others	11%

Source: Survey conducted by the Chief Scientist's office at the Health Ministry.

Conclusions

Health-related R&D in Israel has not been measured separately in the past, and some additional details had to be collected before the above estimates could be made. However, it is planned to start publishing detailed estimates of health-related R&D in the framework of the estimates on national expenditures on health and of national expenditures on R&D.

A number of lessons were learned during the collection of additional information for the estimates of health-related R&D and information on the demand for such estimates:

- Information on R&D in the framework of hospital work is not readily available and it seems that it is not sufficient to conduct a survey of heads of departments – a survey of employees at hospitals is necessary. It seems especially difficult to obtain reliable estimates of R&D by researchers who are employed simultaneously at hospitals and at universities, and there may even be problems of double counting since separate surveys are made of universities.

- It seems to be important to distinguish between clinical research and clinical trials. Clinical trials conducted for pharmaceutical companies have increased rapidly in Israel in recent years, but according to the Chief Scientist at the Health Ministry, such trials should not automatically be included in R&D.

- The usefulness of the estimates of health-related R&D depends upon the classifications used. It would be useful to adopt the classifications (with some modifications) already used by the Health Ministry according to organic specific diseases, clinical category and scientific, medical and methodological approach (see Annex 1). The use of a similar classification would enable links to be made to other data collected by the Health Ministry and thus add analytical possibilities.

- Finally, it seems to be important to have some indications of the quality of R&D, for example, separate information on peer-reviewed funding or a link to data on patents.

Annex 1

DATABASE OF THE CHIEF SCIENTIST'S OFFICE AT THE HEALTH MINISTRY

The Chief Scientist's office at the Health Ministry has established a database with annual data on researchers since 1994. The data in this database are collected via a special survey and comprise close to 1 500 scientists. The information collected for each scientist is:

1. Academic affiliation and rank (if any), professional degree.
2. Hospital affiliation (if any).
3. Discipline of training.
4. Research interest.
5. Principle area of research activity.
6. Titles of current research project.
7. Key words describing research activities.
8. Classification of research activities according to:
   (a) Organic Specific Diseases.
   (b) Clinical Category.
   (c) Scientific, Medical and Methodological Approach.
9. External funding sources.
10. Patents.
11. Publications, including keywords and co-authors.
12. Scientific collaborators.
13. Address.

The detailed classification of health-related R&D used is as follows:

14. Ageing.
15. Autoimmune.
16. Biotechnology.
17. Biotechnical.
18. Cancer.
19. Cardiology.
20. Dentistry.
21. Dermatology.
22. Diabetes.
23. Drug and Pharmacology.
24. Environmental Health.

25. Fertility.
26. Gastroenterology.
27. Genetic Diseases.
28. Genetic Techniques.
29. Health Policy and Epidemiology.
30. Haematology.
31. Hepatology.
32. Hormone.
33. Immunomodulation.
34. Infectious Diseases.
35. Lasers in Medicine.
36. Membranes.
37. Microbial Products.
38. Musculoskeletal.
39. Neuronatal.
40. Neurology and Neuroscience.
41. Nuclear Medicine.
42. Oncogenes.
43. Otolaryngology.
44. Pain and Anaesthesiology.
45. Paediatrics.
46. Primary Care.
47. Psychiatry and Psychology.
48. Pulmonology.
49. Rehabilitation.
50. Renal.
51. Retroviruses (HIV and others).
52. Rheumatology.
53. Surgical.
54. Toxicology.

Cross-classification by organ-specific diseases:

55. Cardiovascular.
56. Connective Tissue Diseases.
57. Dentistry.
58. Dermatological.
59. Endocrine System.
60. Gastrointestinal.
61. Gynaecological and Reproductive System.
62. Haematology.
63. Liver and Related.
64. Muscuskeletical.
65. Neurological Diseases.
66. Ophthalmologic.
67. Otolaryngology.
68. Psychiatry.
69. Respiratory System.
70. Urological, Nephrological.

Cross-classification by clinical categories:

71. Ageing.
72. Degenerative Diseases.
73. Endocrine System.
74. Genetic Diseases.
75. Iatrogenic Disorders.
76. Immunological and Autoimmune Diseases.
77. Infectious Diseases.
78. Metabolic and Physiological Diseases (including Nutrition).
79. Neonatal and Developmental Diseases (Paediatrics).
80. Neoplastic Diseases.
81. Psychiatric Disorders.
82. Toxicology and Environmental Diseases (also Occupational).

Cross-classification by methodological approach:

83. Anaesthesia.
84. Biochemistry.
85. Biostatistics.
86. Cell Biology.
87. Chemistry.
88. Diagnostics, Laboratory Medicine.
89. Epidomiology.
90. Genetic Diseases, Genetic Engineering.
91. Health Education, Health Economics, Health Policy.
92. Imaging, Computers, Computer Imaging.
93. Immunology.
94. Medical Biotechnology and Biomedical Engineering.
95. Microbiology.
96. Molecular Biology.
97. Morphology, Anatomy, Histology.
98. Pharmacology, Pharmaceutics.
99. Physiology.
100. Primary Care.
101. Psychological, Behavioural.
102. Radiobiology, Nuclear Medicine, Laser Medicine.
103. Rehabilitation.
104. Surgical Procedures, Plastic Surgery.
105. Therapy.
106. Transplantation.

Annex 2

QUESTIONNAIRE FOR A SURVEY OF RESEARCH AND DEVELOPMENT AT HOSPITALS

Confidential: The data will be used for statistical purposes only and will not be published in any way that allows the respondent to be identified.

If any explanations or additional information are needed, please contact:

Definition of Research and Development: Systematic and original activity intended to create *new* scientific or technological knowledge or to develop *new applications* of existing scientific or technological knowledge.

Are you engaged in research and development (R&D) in the framework of your work at the hospital?

Yes – continue to fill out the questionnaire

No – go to the last question

How is your work on R&D financed? ☐

One: General hospital budget ☐

Two: R&D hospital funds ☐

Three: External R&D funds (not included in the hospital budget) ☐

Four: University budget ☐

Five: Other, please provide details____________________

Please provide details on the share of your work at the hospital used for the following activities:

Description of activity	Percents
Patient care	
Basic research	
Applied research	
Clinical research	
Clinical trials	
Teaching – including lectures, preparation of lectures, tutoring of students	
Other activities such as administration, consultancy	
Total activities	100%

Please, provide estimates of the distribution of your work time between research areas:

Research area	% time used on R&D

Research areas according to attached list (the list to the respondent will show the classification shown below).

Information about the respondent:

One: Position at the hospital:

Two: Doctor/researcher

Three: Technician/nurse/laboratory worker

Four: Other

Qualifications:

One: Ph.D. or higher

Two: Other university degrees

Three: Other higher education

Four: High school

Five: Other

Proposed supplementary questionnaire to head of departments at hospitals

Confidential: The data will be used for statistical purposes only and will not be published in any way that allows the respondent to be identified.

If any explanations or additional information are needed, please contact:

____

Definition of Research and Development: Systematic and original activity intended to create *new* scientific or technological knowledge or to develop *new applications* of existing scientific or technological knowledge.

Please provide information on the number of employed persons in each category in terms of FTE's in your department financed by the general hospital budget in the year ______ and the percent of work time used for R&D

	FTEs	% time engaged in R&D
Doctors/researchers	____________	____________
Technicians, nurses, laboratory workers	____________	____________
Other employed persons	____________	____________

Please, provide information on the number of employed persons in your department financed by the R&D funds in each category in terms of FTEs in the year_____ by type of fund.

a. R&D hospital funds.

	FTEs
Doctors/researchers	____________
Technicians, nurses, laboratory workers	____________
Other employed persons	____________

b. External R&D funds.

	FTE's
Doctors/researchers	____________
Technicians, nurses, laboratory workers	____________
Other employed persons	____________

Please provide details on the share of the work in your department used for the following activities:

Description of activity	Percents
Patient care	
Basic research	
Applied research	
Clinical research	
Clinical trials	
Teaching – including lectures, preparation of lectures, tutoring of students	
Other activities such as administration, consultancy	
Total activities	**100%**

Please provide estimates of the distribution of the work time in your department between research areas:

Research area	% time used on R&D
____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________

Research areas according to attached list (the list to the respondent will show the classification shown below).

Does your department function as a teaching/training unit for a university?

Yes – for____________________________

No

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Chapter 11

MEASURING HEALTH R&D IN NORWAY

by

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This chapter was prepared specially to contribute Norwegian experience to the discussion of the problems of measuring heath R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in Norway.

Summary description of the national health science and innovation system (HSIS), its core and peripheral components and national specificities

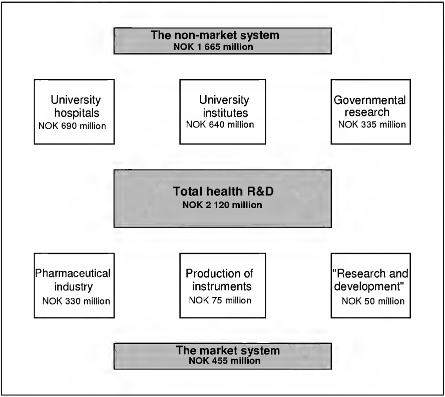
The starting point for a brief description of the Norwegian health science and innovation system (HSIS) could be R&D expenditure in medicine and health, based on R&D statistics for the latest available year (1997) (Figure 11.1). The Norwegian Institute for Studies in Research and Higher Education (NIFU) both collects R&D statistics for the higher education sector and the government sector and co-ordinates national R&D statistics, including for the business enterprise sector. Statistics Norway collects R&D statistics for the business enterprise sector.

A total of NOK 2 120 million was spent on R&D in health sciences in 1997. This is approximately 12% of total Norwegian R&D expenditure. Figure 11.1 presents total health R&D expenditure by performer, showing that approximately 80% was carried out in the non-market system, the rest in the market system.

The non-market system

In Norway, the non-market system comprises the Higher education and Government sectors. The *Higher education sector* (HES) has a dominating position, representing about 80% of R&D expenditures in this field of science in 1997. The core institutions of the Norwegian health science and innovation system are the four universities (including their university hospitals), which performed 95% of all R&D in health sciences in the HES in 1997. The remaining 5% is carried out mainly at the 26 *state colleges* established in 1994 through the amalgamation of about 100 regional colleges offering lower-degree education (2-4 years) in teaching, engineering, nursing, etc.

Figure 11.1. **Total expenditure on health R&D in Norway, by performance – 1997**



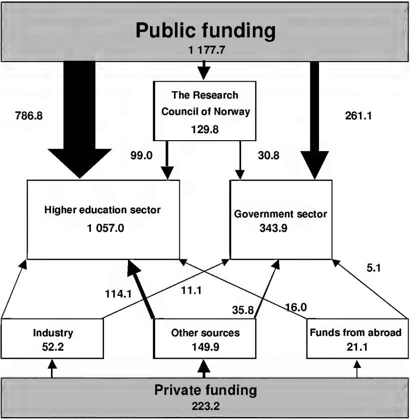
Source: Norwegian Institute for Studies in Research and Higher Education, and Statistics Norway.

In 1997, more than half of health R&D in the HES took place at the university hospitals, which include both university institutes situated at the hospitals and ordinary clinical departments. Some 20 hospitals/medical units are included, varying considerably in size.

Health R&D in the *Government sector* is performed in research institutes, most of which are directly placed under and financed by the Ministry of Health and Social Affairs. The institutes are of very different size, with two or three institutions dominating R&D performance. The Government sector also includes hospitals/clinics outside the university system. These units are surveyed every ten years and estimates are made for the statistical years in between surveys.

Figure 11.2 shows the flow of funds into health R&D in the non-market system. Public sources financed 84% of the health R&D performed in the non-market system in 1997. The Ministry of Education, Research and Church Affairs is the main public source for R&D finance, providing 41% of total public expenditure on R&D in the HES and Government sector as a whole. The Ministry is also responsible for approximately one-third of the budget of the Research Council of Norway. However, when it comes to health R&D, the Ministry of Health and Social Affairs plays an important role, contributing about 40% of public finances for health R&D in the non-market sectors. Public funding also includes contributions from counties and municipalities.

Figure 11.2. **Current expenditure on health R&D in the Norwegian non-market system, by source of funds (HES and Government sector – 1997)**
NOK million



Note: When reporting statistical data on R&D in an international context, the Norwegian "institute sector" is reclassified. This implies including industry-directed institutes in the business enterprise sector. The remaining public institutes thus constitute the government sector. Health R&D in the OECD government sector is not broken down to the same levels as the national institute sector. For this reason, when presenting data on R&D expenditure by source of funds, the "institute sector" represents "government sector" in this paper. The difference in total R&D expenditures is only approximately NOK 20 million.
Source: Norwegian Institute for Studies in Research and Higher Education.

One of the funding categories included in private funding, "other sources", plays an important role in medical and health sciences compared to the other fields of science. Other sources cover mainly funding from private foundations and charity organisations.

The Ministry of Education, Research and Church Affairs is responsible for public education institutions, including education at all levels, research and supporting activities. The Ministry of Health and Social Affairs plays an important role in health R&D in that it is responsible for the Norwegian health services. This Ministry funds all activities at the state hospitals (university clinics), including research. In addition, R&D performance at county municipal hospitals in the university system is calculated from a special grant from the Ministry (see section on *Measuring health-related R&D in the non-market/public sector*). Health research institutions in the Government sector are placed under and receive their main funding from the Ministry of Health and Social Affairs. R&D at non-educational county municipal hospitals in the government sector are funded by the counties.

All Norwegian institutions of higher education are linked through the so-called "Network Norway". This concept implies that the higher education institutions will be further developed within a national integrated system. "Network Norway" will require closer co-operation and a better division of labour on teaching courses and research between the various institutions.

One example of institutional links by topic of R&D is the organisation of health education and research at the University of Oslo. This takes place at several institutions/hospitals, and institutes engaged in similar medical topics are linked in "institute groups", for example the Institute Group on Laboratory Medicine.

The main demander for data on R&D is the Ministry of Education, Research and Church Affairs. The Research Council of Norway (see also section on *Measuring health-related R&D in the non-market/public sector*), Medicine and Health Division, also requires data on health-related R&D, as it acts as advisor to the government on medical R&D matters.

The market system

The R&D statistical survey in the market system, or business enterprise sector (BES), is based on the enterprise as the survey unit. This makes it possible to draw out information on R&D at enterprise level before aggregating to a higher level.

Approximately 20% of total R&D expenditure on health sciences in 1997 was related to the market system. Around 70% was spent by enterprises in the pharmaceutical industry, slightly over 15% by enterprises producing medical instruments and the rest (*estimated*) by units classified in the OECD industry category "research and development". Almost 90% of health R&D expenditure in the BES is funded by industry itself, while public sources account for less than 5%.

The BES R&D questionnaire includes questions on national and international collaboration, as well as on extramural expenditures; R&D purchased from other national enterprises, research institutes or universities or from units abroad. These "collaborating" units may be looked upon as peripheral elements in the market system.

Health-related R&D in national S&T budgets and in GBAORD

Norwegian GBAORD covers all budget appropriations or outlays for R&D at central government level. All budget items are reviewed for R&D content, and R&D shares are estimated by applying R&D coefficients derived from the R&D statistical surveys. For some budget items, other sources are consulted to establish the R&D coefficients.

The Ministry of Health and Social Affairs is the core funder of health as an SEO in GBAORD. In the performer-reported tables, funds from the central government budget are treated as "own funds" in the Government sector and as "GUF"or as direct government funds in the Higher education sector. GBAORD is distributed between objectives according to the budget items' principal R&D objective. Funding from the Ministry of Health and Social Affairs is included in the "health" category, whereas GUF is included in "advancement of knowledge". As a consequence, all university medical faculties are classified in the "advancement of knowledge" category in GBAORD.

Health-related R&D for developing countries is included to the extent that it represents a separate item in the budget. Funding by the ministries' underlying agencies is not included.

In terms of sector of destination, the HES is the recipient of about 40% of state budget's "health" category. Apart from main objective and sector of destination, sub-classifications are not available.

Measuring health-related R&D in the non-market/public sector

This paper is too short to provide a detailed description of the methodology used to compile R&D statistics, but we would like to highlight the factors that we consider to be important for health R&D. In general, Norwegian R&D statistics are produced in line with the recommendations of the *Frascati Manual.*

The statistical surveys are conducted every two years. The whole *Higher education sector* is surveyed, including departments at all university hospitals. Each individual department or corresponding basic unit receives the questionnaire for reporting R&D activities. Supplementary sources of information are surveys of staff members' use of time, information on both personnel and expenditure from an institution's central administration, the Research Council of Norway and medical foundations.

The key to identifying health-related R&D is that each R&D performing unit (institute/department) is attached to a specific field of science, based on information on the main subject of R&D performed. In medical and health sciences, information is available by field of science at a disaggregated level; this implies that data can be presented on the different subjects within medicine and health (Table 11.2). It also allows units which are not attached to medical faculties to be included in the health field, and vice versa. Thus, field of science is not linked to the institution or faculty, but to the R&D *performing unit.*

As a rule, research in the medical sciences in the HES is performed at universities and university hospitals, while health R&D is performed at the state colleges. In the Government sector, some institutes are classified as performers of health R&D, others as performers of medical sciences.

The *Government sector* is also covered by complete surveys. Questionnaires are sent to all research institutes and other institutions expected to perform R&D. In addition, estimates of R&D resources at museums and at non-university hospitals are included.

Coverage and R&D content

As pointed out above, R&D surveys in the non-market system are total surveys. For the few higher education institutes which do not fill in the questionnaire, information is constructed by means of the register of all R&D personnel in the non-market system, data from central administrations and information from the Research Council of Norway and the main private funders of health R&D.

Table 11.1 shows the health R&D carried out in the HES at university institutes and university hospitals and the role of the funding bodies. GUF is composed of funding from the Ministry of Education, Research and Church Affairs and the Ministry of Health and Social Affairs. The Research Council of Norway funds research training for doctoral degrees and contributes to the financing of scientific equipment. However, funding from the Research Council is less important for health sciences than for the other fields of science in the HES. The category "other sources" is important for health R&D. Private charity foundations (*e.g.* the Norwegian Cancer Society, the Norwegian Council of Cardiovascular Diseases) are the main bodies in this category.

Table 11.1. **Total expenditure on health R&D in the HES, by source of funds – 1997**
NOK million

Source of finance	University institutes	Hospital institutes	Total
General University Funds (GUF)	437.0	525.9	962.9
Ministry of Education, Research and Church Affairs	434.6	168.7	603.3
Ministry of Health and Social Affairs	-	357.2	357.2
Other ministries	2.4	-	2.4
External funding	204.8	161.2	366.0
Ministry of Education, Research and Church Affairs	1.5	0.3	1.7
Ministry of Health and Social Affairs	19.6	18.1	37.7
Other ministries, counties, municipalities	26.9	6.5	33.4
The Research Council of Norway	72.5	40.5	113.0
Other sources	51.9	67.2	119.1
Business enterprise	19.1	24.4	43.5
Funds from abroad	13.3	4.2	17.5
Total	641.8	687.1	1 328.9

Source: Norwegian Institute for Studies in Research and Higher Education.

Hospitals

Some 20 hospitals and medical institutions are included in the HES as university hospitals. They vary by size and medical field. Some are state (central government) hospitals, others are administered by the counties. For state hospitals, R&D activities are financed through their own budget chapters in the state budget. For county municipal hospitals, a special allocation from the Ministry of Health and Social Affairs covers research, teaching and related activities. The R&D share for these activities is estimated by NIFU using specific percentages, which vary considerably between hospitals. The estimates are based on the number of personnel paid by hospital (mainly physicians at different levels) and engaged in R&D and their share of R&D working time. These R&D coefficients are based on a special survey on medical R&D carried out in 1990, which included all personnel engaged in medical R&D. The results were confirmed by a later special survey at the university hospitals (1996).

Hospitals, medical centres and clinics outside the university system, (slightly over 100 elements), are included in the Government sector. These units are surveyed every tenth year, and estimates are made for the intervening statistical years.

Classification, breakdown, etc.

Institutions classified as university clinics are included in the HES, whereas other hospitals are placed in the Government sector, in line with *Frascati* recommendations. Standard *Frascati* breakdowns are directly available for health sciences (by source of funds, type of cost, type of activity, etc.). National publications present detailed classifications by medical topic. Table 11.2 gives an example of this type of breakdown. A further breakdown by funding source is also available. Thus, we are able to identify R&D funding from the European Commission, which is interesting in many contexts.

Table 11.2. **Total R&D expenditure in clinical medicine at university hospitals, by source of funds and subject – 1997**
NOK million

Subject	Industry	Public funding	The Research Council of Norway[1]	Other sources[2]	Funds from abroad	Total
Neurology	0.4	18.5	1.1	1.4	0.1	21.6
Dermatology	0.1	23.3	0.4	0.5	-	24.3
Gynaecology and obstetrics	-	15.1	0.4	0.5	-	16.0
Psychiatry	0.2	29.8	3.9	1.3	-	35.1
Paediatrics	1.1	21.8	1.8	6.2	1.1	32.0
Rheumatology	0.6	3.8	1.3	3.2	-	8.9
Oncology	0.5	20.4	-	6.7	-	27.5
Radiology	-	18.3	-	0.2	-	18.5
Physical medicine and rehabilitation	-	1.3	0.3	0.5	-	2.1
Anaesthesiology	0.3	7.4	0.4	0.2	-	8.3
Internal medicine	9.8	76.5	7.9	13.0	0.3	107.6
Surgery	3.8	74.0	4.3	5.5	0.4	87.9
Clin. med. nec	0.1	6.1	0.3	0.2	0.0	6.8
Total	16.7	316.3	22.2	39.5	1.9	396.6

1. The Research Council of Norway is a public source.
2. Other sources cover mainly funding from private foundations and charities.
Source: Norwegian Institute for Studies in Research and Higher Education.

Data on extramural expenditure by destination are available for the Government sector, but not for the HES. Data on project co-operation with international institutions (number of projects, expenditures) are also available for the Government sector. During the 1990s, NIFU undertook annual surveys on international research collaboration on behalf of the Ministry of Education, Research and Church Affairs. GBAORD data have been useful for these surveys.

NIFU has conducted a number of surveys on staff mobility in various fields of the public sector. The register of research personnel is basic to these surveys. The register includes all scientific personnel (ISCED 5A and 6) in the HES and Government sector (see section on Health-related GERD and R&D personnel: level and structure).

Measuring health-related R&D in the market/industry sector

R&D statistical surveys in the business enterprise sector (BES) are conducted every two years by Statistics Norway. NIFU is responsible for integrating the results in the R&D totals for Norway and for reporting data to international organisations (OECD, Eurostat and Nordic Statistics).

As of 1995, all enterprises with more than ten employees are included in the survey, although some of these figures are estimated. The survey unit is an enterprise whose main economic activity is tied to an industry sub-group. This makes it possible to gain information on product fields; financing, type of costs, number of employees, etc. Product groups relevant for health R&D are: pharmaceutical industry; and production of medical equipment, as well as some enterprises in the "research and development" group.

Statistics Norway has commented that the register of enterprises (based on NACE) may be used for picking out elements from the health or medicine point of view and then aggregating data to the area required. Standard *Frascati* classifications are available for the NACE groups. For figures on R&D in the BES or market system, see Figure 11.1 and Tables 11.3 and 11.4.

Innovation surveys have been carried out by Statistics Norway for the years 1992 and 1997. Survey units are identical to the enterprises in the R&D surveys, and information is available by NACE group; these include innovation expenditure, number of innovative enterprises, motivation for innovation activity, collaborators in the innovation activity, etc.

Health-related GERD and R&D personnel: level and structure

Tables 11.3 and 11.4 show total R&D resources for health R&D in 1997; expenditure and personnel. As mentioned before funding may be further broken down.

Statistics on R&D personnel in the HES and Government sector are based on NIFU's register of research personnel, scientists and engineers. The register is updated every second year, prior to the R&D surveys. Detailed information on R&D personnel is available. The register forms the basis for calculating R&D expenditure in the HES. In national publications, R&D personnel in the HES are presented by position (Table 11.5) and scientific field or institution. For the calculation of FTEs, each position or group of positions has its unique R&D coefficient, derived from time-budget surveys. The R&D coefficients differ depending on field of science, technology and institution.

Table 11.3. **Total expenditure on health R&D, by sector of performance and source of funds – 1997**
NOK million

Sector of performance	Total	Industry	Public funding	Other sources	Abroad
Higher education sector	1 328.9	43.5	1 146.4	121.4	17.5
Government sector[1]	343.9	11.1	291.9	35.8	5.1
Business enterprise sector[2]	454.0	404.5	20.1	-	29.4
Total	2 126.8	459.1	1 458.4	157.2	52.0

1. Current expenditure, see note **1** to Figure 11.2.

2. Pharmaceutical industry and production of medical instruments. Also included is health R&D from the category "research and development", which accounts for approximately NOK 50 million, and estimates by source of funds made on the basis of total R&D services.

Source: Norwegian Institute for Studies in Research and Higher Education, and Statistics Norway.

Table 11.4. **Total R&D personnel in health sciences, by sector of employment and formal qualification – 1997**
FTE

Sector of performance	FTE all personnel	FTE university degrees
Higher education sector	1 863	1 211
Government sector	586	382
Business enterprise sector[1]	531	371
Total	2 980	1 964

1. Pharmaceutical industry and production of medical instruments. In addition (not included in the figures), health R&D accounts for approximately NOK 50 million (personnel not estimated) from the category "research and development".

Source: Norwegian Institute for Studies in Research and Higher Education and Statistics Norway.

Table 11.5. **Number of academic staff (head-count) in the HES, by position – 1997**

Position	All fields of science	Health sciences
Professor	2 062	365
College reader	93	2
Associate professor	2 545	213
Assistant professor	816	55
Senior lecturer	154	13
University/college lecturer	3 081	525
Researcher, post.doc. fellowship-holders	933	212
Physicians at university hospitals	1 093	1 093
Fellowship holders	2 608	592
Scientific assistants	334	35
Student fellowship-holders	66	30
Total	13 785	3 135

Source: Norwegian Institute for Studies in Research and Higher Education.

Lessons for national and international survey practice and for the *Frascati Manual*

The greatest national challenge concerning health R&D statistics relates to resources for medical R&D at the university hospitals and also in other hospitals/centres.

In the 1990s the university hospitals have received a block grant from the Ministry of Health and Social Affairs to cover research and experimental development, education of medical students and advanced medical treatment. NIFU calculated the share of this grant for R&D on the basis of time-budget surveys of physicians, mean wages for these types of personnel and other factors, such as differences in health expenditures in different regions of Norway.

In the government budget for 1999, the Ministry of Health and Social Affairs decided to allocate a specific amount of money for R&D in the university hospitals. This allocation lies well below the expenditures we calculated at NIFU for medical R&D at university clinics in the last years' R&D statistics. We assume that the Ministry has not taken into consideration the problems of R&D performed outside ordinary working hours, overhead expenditures, etc. Thus, this is the most important task we have to deal with in relation to health R&D in the national 1999 statistics.

We also feel the need to examine in more depth the calculation of R&D FTE for personnel performing R&D at the university hospitals. Many of these employees occupy more than one position: full-time chief physician/part-time professor or other position combinations. In Norway, the normal working week is 38 hours. Time-budget surveys for university-tenured personnel indicate a mean of about 50 hours per week. A special survey of the university hospitals carried out in 1996 showed that more than 50% of the personnel performing R&D at hospitals spend more than 50 hours a week at work. According to the *Frascati Manual*, which we follow in the Norwegian R&D statistics, a person can only represent one full-time equivalent. Thus "free-time" R&D is also included. It is of great importance to deal with these matters in an international context as this notion is basic for compiling R&D statistics.

Concerning R&D performed in other hospitals/centres (included in government sector), other questions arise, such as how to define institutions and activities, how to make forecasts/estimations. From bibliometric studies, it becomes clear that many workers in such organisations perform R&D and/or write articles.

The central authorities and the Research Council of Norway often request international R&D statistics in order to make cross-country comparisons. There is a special interest for data on R&D by field of science. However, presenting this type of information presents a number of problems, in terms of deficiency of data, coverage, sector classification, etc. This is especially true for the health sciences, which involve hospitals and thus R&D performed by physicians paid over hospitals' budgets.

Annex 1

LIST OF NORWEGIAN HEALTH-RELATED R&D SURVEYS

The Norwegian Institute for Studies in Research and Higher Education has conducted a number of surveys on health R&D. The majority are based on national R&D statistics, including the Register on Research Personnel. A separate survey (Sundnes and Mørland, 1997) which covered all physicians at university hospitals, was carried out in 1997. With one exception (Sundnes, 1996), the publications are in Norwegian.

The following publications were issued during the 1990s; the Norwegian titles have been translated into English:

Nerdrum, L. (1999), "Recruitment to Research within Medicine and Health Disciplines. Description of Today's Situation and Estimated Needs towards Year 2015", Report 5/99, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Olsen, T.B. (1991), "Research at Norwegian Hospitals. A Mapping of R&D Activities at Hospitals Outside the University System, Including a General View on Total Resources for Medical R&D in Norway", Report 5/91, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Skodvin, O.J. (1991), "Recruitment to Medical Research. Status and Perspectives Towards Year 2000", Report 6/91, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Sundnes, S.L. (1996), "Research Fellowships for Medical Students in Norway", *Medical Education* 30, pp. 459-60.

Sundnes, S.L. (1997), "Resources for Medical R&D. Extract from the National R&D Statistics with Emphasis on 1995", NIFU skriftserie No. 29/97, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Sundnes, S.L. and K.W. Maus (1997), "Resources for Medical R&D 1993. Extract from the National R&D Statistics", NIFU skriftserie No. 7/97, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Sundnes, S.L. and B. Mørland (1997), "Conditions for Medical R&D at University Hospitals 1996", NIFU skriftserie No. 8/97, Norwegian Institute for Studies in Research and Higher Education, Oslo.

Chapter 12

RESEARCH IN THE SPANISH HEALTH SERVICES

by

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This chapter was prepared specially to contribute Spanish experience to the discussion of the problems of measuring heath R&D. This is a translation of the French original.

Introduction

The key institution of the Spanish health research system is the Carlos III Research Institute, which reports to the Ministry of Health and Consumer Affairs. In 1997, it received about ESP 10 000 million for R&D from the budget, of which ESP 7 700 million were for its own activities and ESP 2 300 million were contributed to the Fund for Health Research (FIS). This fund is the main government tool for financing research in other units specialising in the area, the Higher Council for Scientific Research (CSIC), the universities, the public hospitals belonging to the social security system and also the Councils of the Autonomous Regions charged with health affairs by central government.

Problems of measuring R&D in the health sciences

The data by field of science are obtained by distributing all the variables in a unit's response to the questionnaire on the basis of a percentage breakdown of intramural R&D expenditure provided by the respondent.

Determining the resources devoted to medical R&D by the core institutes involved (Carlos III Institute, CSIC) does not pose any serious difficulties. For the Higher education sector, problems only arise for estimating the share of general public support for universities, which should be attributed to R&D (GUF). The biggest challenge is to obtain reliable data on R&D in hospitals.

In most public hospitals there is no post to oversee all R&D activities, only for a co-ordinator to manage grants from the FIS. This person is generally unaware of how much is spent on R&D out of "General Hospital Funds". To obtain this information, each doctor would have report the breakdown of his/her activities between health care, teaching, R&D, administration and other. These percentages could be used to calculate the FTE which the doctor devotes to R&D and also the share of his/her salary which could be attributed to R&D. Furthermore, hospital research teams take on R&D contracts directly from pharmaceutical companies. These arrangements are not transparent as they are often not declared to hospital management and information about the transactions may be deliberately withheld. It follows that the co-ordinators do not control these direct research funds from the pharmaceutical industry.

In consequence, the responses to the R&D survey by hospitals are unsatisfactory. They often contain inconsistencies, for example between the resources reported for expenditure and for personnel or between consecutive years. For this reason the survey authorities often have to re-estimate responses from hospitals with no guarantee that the new figures are better than the old ones, given the lack of information about this sector.

A possible solution

We would like to propose that the *Frascati Manual* recommendation that time-budget surveys should be undertaken of university teachers be extended to hospital doctors. In this way, it would be possible to obtain more reliable estimates of General Hospital Funds for research. Also, if the anonymity of respondents were guaranteed, it would be possible to identify funds coming from the pharmaceutical industry about which we currently have no information.

Chapter 13

MEASURING HEALTH-RELATED R&D IN THE UNITED KINGDOM

by

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Department of Health

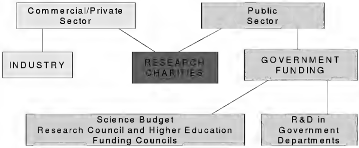
This chapter was prepared specially by the English Department of Health to contribute their experience to the discussion of the problems of measuring health R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in England or in the United Kingdom. The data should not be used or redistributed without the explicit permission of the Department of Health.

The national health science and innovation system

There are three sources of funding for health-related R&D in the United Kingdom:

- The market (commercial or private) sector.
- The charity sector (derived from both private and public donations).
- The public (government) sector.

Figure 13.1. **UK sources of funding for health-related R&D**


Commercial/Private Sector
Public Sector
INDUSTRY
RESEARCH CHARITIES
GOVERNMENT FUNDING
Science Budget Research Council and Higher Education Funding Councils
R&D in Government Departments

The market sector

It is estimated that industry spends around GBP 2 500 million a year on health-related research in the United Kingdom.[1] The bulk of this money comes from the pharmaceutical industry.

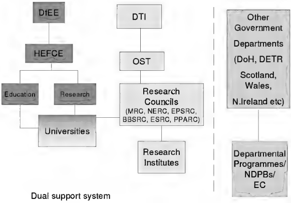
The charity sector

Medical and health related charities spend an average of GBP 415 million a year on R&D in the United Kingdom[2]

The public sector

Government support for R&D is provided through the science budget and through separate departmental R&D budgets.[3] The science budget supports research in universities through a dual support system. The Department for Education and Employment (DfEE) provides university research infrastructure funding via the Higher Education Funding Councils (for England, Scotland, Wales and Northern Ireland). The Office of Science and Technology (OST) in the Department of Trade and Industry (DTI) provides funding to the Research Councils which meets the additional costs of research projects and postgraduate training. In 1998/99, public sector funding in England (mainly from Department of Health, Medical Research Council and HEFC-England) for health-related R&D is estimated to be around GBP 1 000 million a year.

Figure 13.2. **Government funding for R&D**


DfEE
HEFCE
Education
Research
Universities
DTI
OST
Research Councils
(MRC, NERC, EPSRC, BBSRC, ESRC, PPARC)
Research Institutes
Other Government Departments (DoH, DETR Scotland, Wales, N.Ireland etc)
Departmental Programmes/ NDPBs/ EC
Dual support system

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[1] Information provided by the Association of British Pharmaceutical Industries (ABPI).

[2] Information supplied by the Association of Medical Research Charities.

[3] In the United Kingdom, certain powers have recently been devolved from Central Government to Scottish, Welsh and Northern Irish administrations. Health is a devolved issue whereas research is reserved to central government. Thus, for example, the Department of Health data cover England while the Medical Research Council data are for the whole of the United Kingdom.

In 1998/99, the Higher Education Funding Council for England (HEFCE) provided GBP 829 million to universities in overall infrastructure funding for research. In the same year, the Office of Science and Technology (OST) allocated GBP 1 340 million in research funds via the Research Councils:

EPSRC (engineering and physics)	GBP 397 million
MRC (medical)	GBP 304 million
BBSRC (biological)	GBP 198 million
PPARC (particle physics and astronomy)	GBP 194 million
NECR (natural environment)	GBP 178 million
ESRC (economic and social)	GBP 69 million

United Kingdom government departments

Government departments fund research and development to support their work on policy development and evaluation in order to ensure that policy is based on reliable evidence of needs and what works best to meet those needs. In addition, departments may fund other research activities required to discharge their statutory responsibilities. United Kingdom government departments involved in S&T expenditure include:

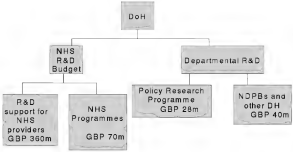
- Ministry of Agriculture, Fisheries and Food
- Department for Culture, Media and Sports
- Ministry of Defence
- Department for Education and Employment
- Department of the Environment, Transport and the Regions
- Forestry Commission
- Department of Health
- Health and Safety Executive
- Home Office
- Department for International Development
- Department of Social Security
- Department of Trade and Industry
- HM Treasury
- Office of Science and Technology
- Northern Ireland Departments
- The Scottish Office and the Scottish Executive
- Welsh Office and the National Assembly for Wales

While some government departments spend a great deal on R&D (*e.g.* Defence), others spend relatively little. For example, the Department for Culture, Media and Sport spends around GBP 11 million a year on S&T, including funding research at the United Kingdom Natural History Museum which aims to further understanding of the natural world.

Research and development in the Department of Health

The Department of Health supports work to meet its needs in policy development and evaluation through the Policy Research Programme. The Department also manages National Health Service R&D funding which is used to support R&D vital to improvements in medicine and health, which is relevant to the National Health Service, and is often undertaken in hospitals, general practice and other health care settings (providers). This research is often funded by other bodies such as research councils and charities. It generates extra costs in the NHS – the Department pays these service support costs through the national R&D budget. The ordinary costs of treating patients are met through general funds, not the R&D budget.

Figure 13.3. **Department of Health R&D funding**


DoH
NHS R&D Budget
Departmental R&D
R&D support for NHS providers GBP 360m
NHS Programmes GBP 70m
Policy Research Programme GBP 28m
NDPBs and other DH GBP 40m

National Health Service R&D funding also funds the NHS R&D programme which aims to identify NHS needs for research and to commission research to meet those needs. Some funds are used to help improve capacity to undertake research – for example, the provision of fellowships and awards to develop research capacity in primary care.[4]

The Department also funds research through its Non-Departmental Public Bodies (NDPBs) such as the National Radiological Protection Board, Public Health Laboratory Service and others.

Current annual expenditure on research and development with the Department:

R&D support for NHS providers	GBP 360 million
NHS R&D programme	GBP 70 million
Policy Research Programme	GBP 28 million
NDPBs and other DoH	GBP 40 million

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[4] The Department of Health is currently revising the arrangements for NHS R&D funding. Details can be found on their Web site at www.doh.gov.uk/research.

Funding for R&D at different tiers of government

In the NHS, R&D funding is within a single stream which is administered nationally and regionally.

At the next tier are the NDPBs, including the Research Councils. The Research Councils are accountable to the Office of Science and Technology (OST) within the Department of Trade and Industry (DTI), not the Department of Health.

Links

Funding for health-related R&D in the United Kingdom is complex and thus a large number of mechanisms, both formal and informal, are used to maintain links between funders and/or between them and research institutions.

Demand for data

Demands for data come from the Office of Science and Technology, the Office of National Statistics, other parts of government and the general public.

Information about projects commissioned by the Department of Health, the NHS or supported through NHS R&D funding can be found on the National Research Register (NRR) at www.doh.gov.uk/research/nrr.htm. This includes data on research title, research questions, methodology, sample group and outcome measures. The following information is not collected routinely:

- Details of costs at project level, except for directly commissioned projects.
- Numbers, or details, of personnel involved in R&D projects.
- Sector of destination of funds (*i.e.* whether the money is spent in universities, NHS, etc).

Accounting to the public for research expenditure frequently involves trying to categorise research within disease-specific categories, or in relation to parts of the body, for example. This can be misleading since there are overlaps in categories (risking under- or over-counting) and contributions from many disciplines.

Health-related R&D in national S&T budgets and in GBAORD

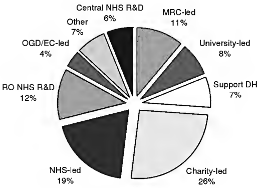
Sector of destination

The Department does not routinely collect data on sector of destination. Much of the expenditure within the budget for R&D support for NHS providers takes place within the NHS itself. Most of the directly commissioned R&D takes place in the university sector.

Sector leading expenditure within the NHS

Figure 13.4 shows how the DH/NHS current expenditure of approximately GBP 500 million is driven by funding.

Figure 13.4. **Department of Health/National Health System expenditure**



Spending by funders on health-related R&D that takes places within the NHS has cost implications for the NHS. The slices on the right-hand side of Figure 13.4 (MRC, Charity, OGD/EC and University-led) are mainly NHS support costs for R&D funded by partner organisations external to the NHS. The other slices represent direct expenditure by DH/NHS on research.

Lessons for national and international survey practice and for the *Frascati Manual*

We would urge the meeting to give careful consideration to the need for caution when comparing data collected at different times, in different ways and for different purposes. In our experience, inter-sectoral comparisons, for example in the United Kingdom between the tertiary education system and the science-base, call for particular caution.

A clear example of this is given in the United Kingdom data collected by ONS using the *Frascati* definitions. This substantially under-counts the Department of Health's R&D by about 10%. In particular, it discounts funds used to support fellowships and funding to underpin doctoral training. The figures given in this paper represent the Department's total figures for R&D. Figures generated for the Department by ONS using the *Frascati* definitions can be viewed at http://www.dti.gov.uk/ost/forwardlook99.

International comparisons are likely to require even greater caution.

Overall, we have no desire to revisit the *Frascati* definition – simply to note that it excludes significant elements of government support for health-related R&D.

Chapter 14

ESTIMATES OF HEALTH R&D EXPENDITURES IN THE UNITED STATES: AN EXPLORATORY DATA COMPILATION

by

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This chapter was prepared specially to contribute American experience to the discussion of the problems of measuring heath R&D. The data were compiled for that purpose and should not be treated as official measures of health-related R&D in the United States.

There are no official statistics on national support for health R&D in the United States. Up until 1995, the National Institutes of Health (NIH) of the US Department of Health and Human Services published the NIH Data Book, in which were estimated such support by source of funds and performing sector. The last published national totals were estimates for 1992 and 1993 and projections for 1994. Since then, the NIH has compiled and released on the World Wide Web estimates of Federal obligations for health R&D. The latest data are "actuals" for 1997 and estimates for 1998 and 1999.

In fiscal year 1997, NIH estimates that Federal agencies obligated USD 15.1 billion for health R&D, of which 76% was received by extramural performers and 24% was used in Federal agency laboratories (see Table 4.1).

GBAORD data (from the NSF publication, Federal R&D Funding by Budget Function: Fiscal Years 1997-1999, NSF 99-315, Arlington, Virginia 1999) indicate that USD 12.7 billion was authorised for Federal R&D related to health in fiscal year 1997. A number of agencies included in the NIH report totals are not included in GBAORD health data. Notably, the NIH table on health R&D funding includes USD 1.1 billion from the Department of Defense, USD 0.3 billion each from the Department of Energy and the Department of Veterans' Affairs, and USD 0.2 billion from the National Aeronautics and Space Administration. These agencies are not listed in the GBAORD health R&D totals presented in the NSF report.

Table 14.1. **Federal obligations for health R&D, by source and performer**
US million

	1997	1998 (est.)	1999 (est.)
Total Federal health R&D obligations	15 081	16 237	17 244
National Institutes of Health	11 993	12 867	13 915
Centre for Disease Control & Prevention	323	359	365
Food and Drug Administration	159	143	141
Health Resources & Services Admin	13	14	14
Agency for Health Care Policy & Research	144	147	171
Other HHS	44	51	50
Department of Agriculture	127	140	148
Department of Defence	1 094	1 249	1 072
Department of Education	24	29	29
Department of Energy	319	368	410
Environmental Protection Agency	124	167	146
Agency for International Development	32	29	33
National Aeronautics & Space Admin.	179	166	212
National Science Foundation	81	74	98
Veterans' Administration	260	300	300
Department of Labor	4	3	4
Department of Commerce	72	57	52
Department of Transportation	9	10	10
Department of Interior	79	66	74
By performer			
Federal intramural	3 601	3 792	4 118
State and local governments	137	144	157
Industry	1 048	1 138	1 198
Higher education	7 773	8 391	8 887
(Medical schools)	(5 025)	(5 435)	(5 746)
FFRDCs	212	214	242
Other non-profits	2 248	2 792	2 570
Foreign countries	62	67	71

Source: US Department of Health and Human Resources, National Institutes of Health, Bethesda, Maryland, (30 November 1999).

A lower bound estimate of *national* R&D health expenditures is compiled in Table 14.2. Consistent with total R&D (GERD) reporting guidelines, these data are derived from performer-reported R&D surveys, to the extent possible.

In 1997, it is estimated that USD 30 billion was spent on health-related R&D in the United States, of which approximately USD 12.3 billion, or 41%, was funded by the Federal government. By these estimates, health R&D accounted for approximately 14% of total GERD in 1997.

The sources for the health R&D estimates in Table 14.2 are:

- *Industry*: NSF Survey of Industrial Research and Development Expenditures. Totals include all R&D reported for Standard Industrial Classification 283 (Drugs) and 80 (Health Services). SIC 283 includes R&D of firms primarily engaged in manufacturing, fabricating, or processing medicinal chemicals and pharmaceutical products, and in the grading, grinding, and milling of botanicals. SIC 80 includes R&D of establishments primarily engaged in furnishing medical, surgical, and other health services to persons, including clinics and hospitals. Commercial labs specialising in biological research are not included. R&D by firms engaged in the manufacturing of professional and scientific instruments are not included.

- *Higher education*: NSF Survey of Research and Development Expenditures at Universities and Colleges. Totals include all R&D expenditures in the biological sciences, medical sciences, bioengineering, and biomedical engineering. R&D expenditures include separately budgeted R&D in academic departments, research centres, medical schools, and hospitals and clinics owned, operated or controlled by universities, and integrated operationally with the clinical programmes of medical schools. R&D totals exclude expenditures on clinical trials.

- *Federally funded R&D centres administered by universities*: NSF Survey of Research and Development Expenditures at Universities and Colleges. Totals include all R&D expenditures in the biological sciences, medical sciences, bioengineering, and biomedical engineering.

- *Non-profit sector (other than higher education):* Preliminary unpublished results from the NSF Survey of Research and Development Funding and Performance by Non-profit Organisations. Totals include all R&D performance expenditures reported by university affiliated hospitals and other voluntary non-profit hospitals, and the R&D expenditures on medical and health sciences reported by independent research institutes. R&D performance by university-affiliated organisations reported by non-profit organisations is intended to exclude R&D expenditures reported by universities.

- *State government agencies*: NSF-funded Battelle Survey of State Research and Development Expenditures. Totals include R&D expenditures on health functions within state government agencies.

- *Federal government agencies*: NSF Survey of Federal Funds for Research and Development. Totals include obligations on intramural R&D performance of Federal government agencies that fund health (functional category 550) R&D and medical and prosthetic research (functional category 703). Identification of these agencies are obtained from GBAORD data, NSF publication, "Federal R&D Funding by Budget Function". Intramural activities include actual intramural R&D performance, and the costs associated with the planning and administration of intramural and extramural R&D programmes by Federal personnel.

Table 14.2. **Health- and medical-related R&D expenditures**
USD million

	1995	1996	1997	1998
United States total R&D performance	183 232	196 540	211 586	226 984
Rough lower-bound estimate of health-related R&D		27 000	30 000	33 000
(Health R&D as a percentage of total R&D)		13.7%	14.2%	14.5%
(Federal share of funding)		(11 600)	(12 300)	
Industry R&D performer survey				
Drugs and medicines, SIC 283 (All sources)	10 215	9 773	11 589	12 571
Health Services, SIC 80 (All sources)	756	D	D	1 207
Offices and clinics of medical doctors, hospitals, medical and dental labs	D	715	D	1 096
Other health services	D	D	49	111
Drugs and medicines, SIC 283 (Company sources)	10 202	9 769	11 586	12 566
Health services, SIC 80 (Company sources)	753	735	679	1 173
Offices and clinics of medical doctors, hospitals, medical and dental labs	737	713	632	1 074
Other health services	16	23	48	99
Non-profit R&D performer survey (preliminary)				
University affiliated hospitals (All sources)[2/]	n.a.	468	460	n.a.
Other voluntary nonprofit hospitals (All sources)	n.a.	857	940	n.a.
Research institutes (Intramural R&D in medical and health sciences, all sources)	n.a.	2 082	2 248	n.a.
Non-profit hospitals (Federal sources)	n.a.	712	767	n.a.
Research institutes (Federal sources, estimated)	n.a.	1 334	1 453	n.a.
Academic R&D performer survey[1/ 2/]				
Biomedical R&D (All sources)				
Biological sciences	3 818	3 891	4 156	4 549
Medical sciences	6 069	6 390	6 855	7 456
Bioengineering/Biomedical engineering	n.a.	n.a.	77	102
Biomedical R&D (Federal sources)				
Biological sciences	2 480	2 519	2,681	2 914
Medical sciences	3 826	4 023	4 286	4 546
Bioengineering/Biomedical engineering	n.a.	n.a.	48	57
Academic FFRDCs performer survey				
Biological and medical sciences/engineering	111	119	161	187
Federal government R&D survey (Intramural R&D)				
National Institutes of Health	2 011	2 160	2 234	2 405
Centers for Disease Control	276	241	237	240
Food and Drug Administration	154	152	139	119
Department of Veterans Affairs	238	254	253	277
State government R&D survey				
State agencies' health R&D (Intramural R&D only)	57	n.a.	n.a.	n.a.

D: Data withheld to avoid disclosing operations of individual organisations.

n.a.: Survey not fielded or level of detail not collected.

1. Includes separately budgeted R&D in: *i)* medical school; and *ii)* hospitals and clinics owned, operated or controlled by universities, and integrated operationally with the clinical programmes of medical schools.
2. R&D performance by university-affiliated hospitals reported by non-profits are intended to exclude hospital R&D included in university-reported R&D totals.

Source: US National Science Foundation/Division of Science Resources Studies, Arlington, Virginia (8 September 2000).

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